Independent Market Research on the Global and Indian MedTech Industry

OCTOBER 2025
FROST & SULLIVAN

DISCLAIMER

The market research process for this study has been undertaken through secondary/desk research and primary research, which involves discussing the market status with subject matter experts.

The research methodology used is a mix of secondary and primary research, where the quantitative market information was sourced from secondary data sources, primary research, and trusted portals. The information is subject to fluctuations due to possible business and market changes. Frost & Sullivan's estimates and assumptions are based on varying levels of quantitative and qualitative analyses, including industry journals, company reports, and information in the public domain.

The data has been collated from publicly available sources such as industry reports, annual reports, company filings, and the Ministry of Corporate Affairs (MCA) database. Forecasts, estimates, predictions, and other forward-looking statements contained in this report are inherently uncertain because of changes in factors underlying their assumptions, events, or combinations of circumstances that cannot be reasonably foreseen. Actual results and future events could differ materially from forecasts, estimates, predictions, or such statements. All financial and operational details for Integris Medtech are for continuing operations and are provided by the company.

Frost & Sullivan has prepared this study independently and objectively and has taken adequate care to ensure its accuracy and completeness. We believe that this study presents an accurate and fair view of the Global and Indian MedTech market (with a focus on Cardiovascular Devices, Clinical Diagnostics, and Scientific Lab Solutions) in selected geographies within the limitations of, among others, secondary statistics and primary research, varying scenarios created due to the macro-economic and demand factors, and it does not purport to be exhaustive. Our research has been conducted with an "overall industry" perspective, and it may not necessarily reflect the performance of individual companies in the industry. Frost & Sullivan shall not be liable for any loss suffered because of reliance on the information contained in this study. This study should also not be considered a recommendation to buy or not to buy the shares of any company or company as mentioned in it or otherwise.

ACRONYMS

Abbreviation	Full Form
ABHIM	Ayushman Bharat Health Infrastructure Mission
AB-PMJAY	Ayushman Bharat Pradhan Mantri Jan Arogya Yojana
AFib	Atrial Fibrillation
AI	Artificial Intelligence
APAC	Asia-Pacific
API	Active Pharmaceutical Ingredient
BD	Becton, Dickinson & Co.
BMS	Bare-Metal Stents
CAD	Coronary Artery Disease
CAGR	Compound Annual Growth Rate
CDSCO	Central Drugs Standard Control Organization
CDx	Companion Diagnostics
CE	Conformité Européenne (French for "European Conformity")
CGM	Continuous Glucose Monitoring
CHE	Current Health Expenditure
CRDMO	Contract Research Development Manufacturing Organizations
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CRO	Contract Research Organizations
CT	Computed Tomography
CVD	Cardiovascular Diseases
D.C.	District of Columbia
DALYs	Disability-Adjusted Life Years
DCB	Drug-Coated Balloons
DEB	Drug-Eluting Balloon
DES	Drug-Eluting Stents
DNA	Deoxyribonucleic Acid
DTC	Direct-to-Consumer
ECG	Electrocardiogram
ELISA	Enzyme-Linked Immunosorbent Assay
EMA	European Medicines Agency
EP	Electrophysiology
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FDS	Faster Diagnosis Standard
FY	Fiscal Year
G7	Group of Seven (Canada, France, Germany, Italy, Japan, the UK, and the US)
GDP	Gross Domestic Product
GE	General Electric

IABP	Intra-Aortic Balloon Pumps
ICD	Implantable Cardioverter Defibrillators
IMF	International Monetary Fund
Inc.	Incorporated
IRDAI	Insurance Regulatory and Development Authority of India
IVD	In Vitro Diagnostics
IVUS	Intravascular Ultrasound
KHB	Shanghai Kehua Bio-Engineering Co.
KKR	Kohlberg Kravis Roberts & Co.
LIS	laboratory information systems
M&A	Mergers and Acquisitions
MDD	Medical Device Directive
MDR	Medical Device Regulation
MedTech	Medical Technology
MNC	Multinational Corporation
MSME	Micro, Small, and Medium Enterprises
NCD	Non-Communicable Diseases
NDHM	National Digital Health Mission
NGS	Next-generation sequencing
NHS	National Health Service
NMP	National Master Plan
NMPA	National Medical Products Administration
NPPA	National Pharmaceutical Pricing Authority
OCT	Optical Coherence Tomography
OEM	Original Equipment Manufacturer
OOP	Out-of-Pocket
PCI	Percutaneous Coronary Interventions
PCR	Polymerase Chain Reaction
PE	Private Equity
PLI	Production-Linked Incentive
PM	Prime Minister
PMA	Premarket Approval
PMDA	Pharmaceuticals and Medical Devices Agency
PM-JAY	Pradhan Mantri Jan Arogya Yojana
POBA	Plain Old Balloon Angioplasty
POCT	Point-of-Care Testing
PPP	Public-Private Partnership
PTCA	Percutaneous Transluminal Coronary Angioplasty
R&D	Research and Development
RNA	Ribonucleic Acid
RoW	Rest of the World

RPM	Remote Patient Monitoring
SMBG	Self-monitoring of Blood Glucose
SMT	Sahajanand Medical Technologies
St.	Saint
STEM	Science, Technology, Engineering, and Mathematics
TAVR	Transcatheter Aortic Valve Replacement
UHC	Universal Healthcare Coverage
UK	United Kingdom
UNICEF	United Nations Children's Fund
US	United States
USA	United States of America
USD	US Dollar
VAD	Ventricular Assist Devices
WHO	World Health Organization

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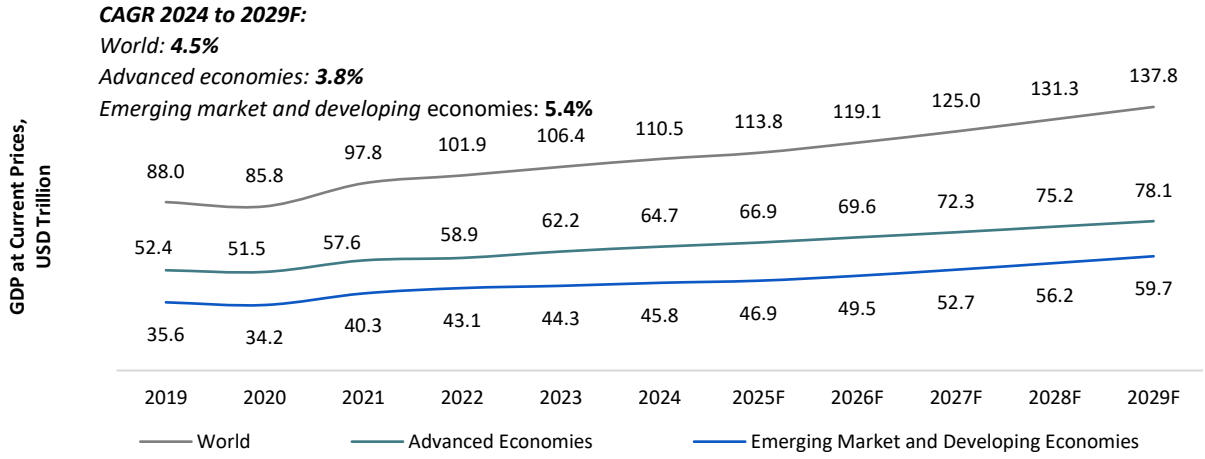
1. Macroeconomic Overview

1.1. Global GDP Growth

The global economy continues to display clear signs of resilience with record-low unemployment rates, despite moderate but persistent inflation, financial risks, and intense geopolitical tensions. The World Economic Forum's forecast places the year-on-year (YOY) global GDP growth forecast at 3.0% in 2025 and 4.7% in 2026, while global headline inflation is expected to decline to 4.3% and 3.5% in 2025 and 2026, respectively. The driving factors for the positive outlook are increasing domestic demands, tight labor markets, favorable business environments, and reductions in policy interest rates.

The confluence of supply chain disruptions caused due to geopolitical scenarios such as the Russia-Ukraine and

Exhibit 1.1: GDP at Current Prices, Global, 2018-2029F



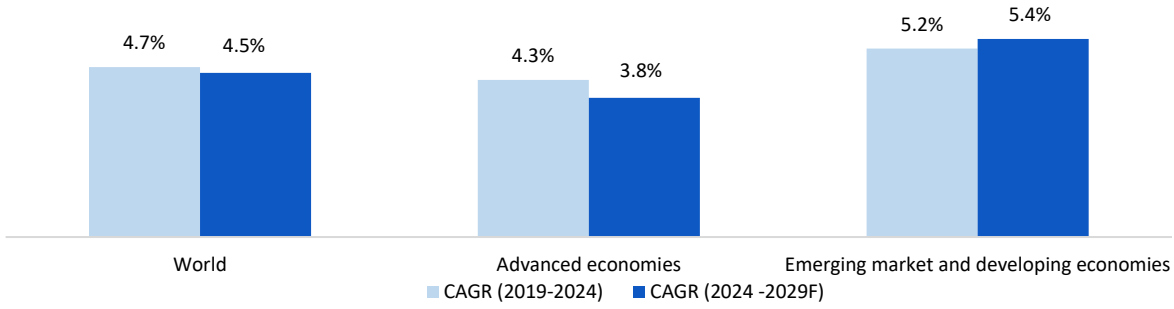
Source: World Economic Outlook-April 2025, Frost & Sullivan

Israel-Palestine conflict has resulted in significant disruptions in markets, sparking a substantial inflationary surge and exacerbating a cost-of-living crisis. Moreover, trade wars through tariff hikes by the US and other countries could have a multifaceted economic impact, with the World Bank identifying several key consequences, including increased risks to global growth, inflation concerns, and disruptions in trade and investment networks. However, it is expected to impact only selected geographies such as China, certain Southeast Asian countries, and Europe. In response, many nations have adopted stricter monetary policies, which, while moderating GDP growth, are still propelling it forward. This anticipated rise is buoyed by emerging markets and developing economies[1], which are expected to achieve a CAGR of 5.4% from 2024 to 2029. Several factors contribute to this GDP growth, including increased private consumption, elevated corporate expenditures, favorable demographics, strengthened balance sheets, improved macroeconomic stability, reducing need for policymakers to tighten monetary policies, and structural policy reforms.

[1] Definition as per International Monetary Fund (IMF). Advanced economies are characterized by high per capita income, diversified exports, and significant integration into the global financial system, and includes countries in Euro Area, G7 major advanced economies, European Union, ASEAN-5, and Other Advanced Economies (Advanced Economies excluding G7 and Euro Area); Emerging Market and Developing Economies is a broad classification that includes countries with lower per capita income and less integration into global markets compared to advanced economies, and includes countries in Emerging and Developing Asia, Emerging and Developing Europe, Latin America and the Caribbean, Middle East and Central Asia, and Sub-Saharan Africa.

GDP of advanced economies is expected to see a slower growth rate (CAGR of 3.8% between 2024 and 2029) as compared to emerging and developing economies. Nevertheless, this marks an improvement from past figures, driven by positive employment prospects in the United States and rising consumption trends in Europe. This optimistic long-term economic outlook is poised to stimulate global investments and bolster demand in vital sectors, such as healthcare.

Exhibit 1.2: CAGR of GDP at Current Prices, 2019-2029F



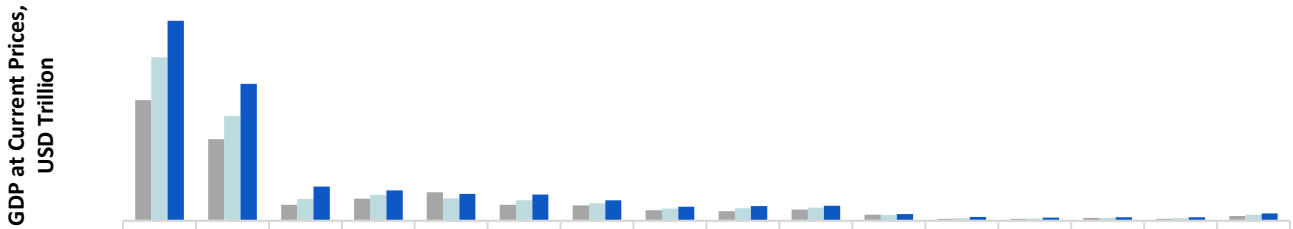
Source: World Economic Outlook-April 2025, Frost & Sullivan

Many emerging economies have strengthened their economic foundations with more resilient balance sheets and lower debt levels. Emerging markets are increasing intra-regional trade and developing their own global value chains, reducing their reliance on traditional developed-market export destinations like the U.S. and Europe. This diversification is making them more resilient to external shocks. Moreover, emerging markets have younger populations and a growing labor force, which provides a strong demographic dividend for economic expansion and consumer demand. Emerging economies in South and Southeast Asia, such as India, China, Vietnam, Indonesia, and the Philippines, are major contributors to the growth.

1.1.1. GDP of G7 Countries and Select Emerging Markets

Advanced economies like the US, Germany, the UK, and France face slower nominal GDP growth compared to emerging economies such as India and China. While the US shows robust growth amid mixed risks, the Euro area faces downward pressure. In Asia, growth impacts vary, with India emerging as the world's fastest-growing major economy.

Exhibit 1.3: GDP at Current Prices, Select Countries, 2019-2029F

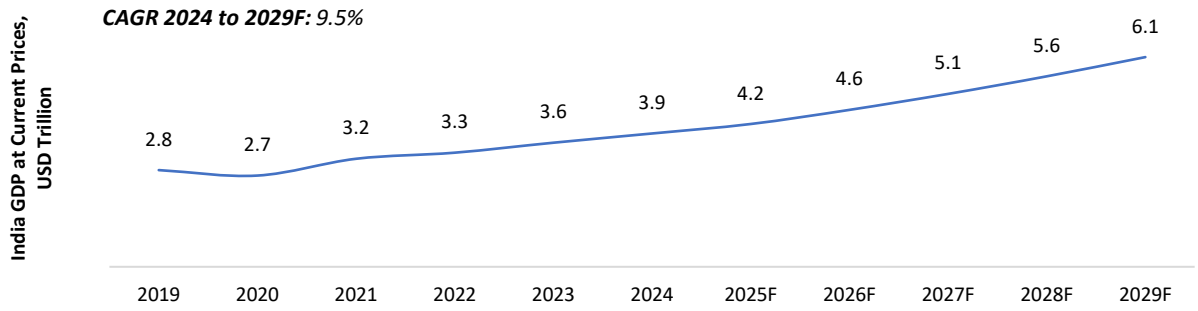


	USA	China	India	Germany	Japan	UK	France	Brazil	Canada	Italy	Indonesia	Philippines	Malaysia	Thailand	Vietnam	Saudi Arabia
2019	21.5	14.6	2.8	4.0	5.1	2.9	2.7	1.9	1.7	2.0	1.1	0.4	0.4	0.5	0.3	0.8
2024	29.2	18.7	3.9	4.7	4.0	3.6	3.2	2.2	2.2	2.4	1.1	0.5	0.4	0.5	0.5	1.1
2029F	35.7	24.5	6.1	5.4	4.8	4.7	3.6	2.5	2.7	2.7	1.2	0.7	0.6	0.6	0.6	1.3

Source: World Economic Outlook-April 2025, Frost & Sullivan

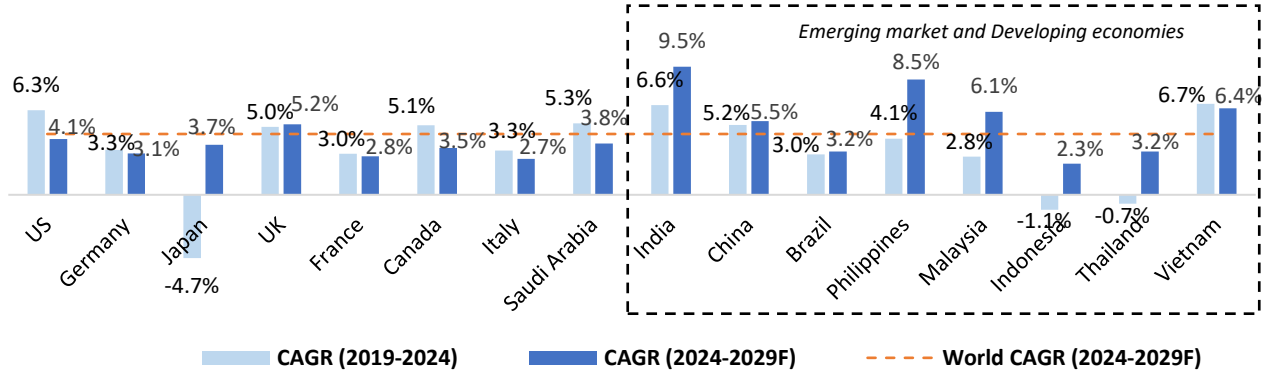
India is among the world's fastest-growing economies of the world. India's GDP is expected to surpass USD 5.0 trillion in 2027 and reach USD 6.1 trillion in 2029, with the economy projected to grow at a CAGR of 9.5% between 2024 and 2029. India is on track to achieve developed economy status by 2047. This goal is backed by domestic and international investments, enhanced global relationships, favorable policies to increase domestic consumption, a thriving MSME (micro, small, and medium-sized enterprise) sector, and targeted reforms such as Atmanirbhar Bharat, which focuses on increasing the country's exports.

Exhibit 1.4: GDP at Current Prices, India, 2019-2029F



Source: World Economic Outlook-April 2025, Frost & Sullivan

Exhibit 1.5: CAGR of GDP at Current Prices, G7 countries and select emerging market and developing economies, 2019-2029F



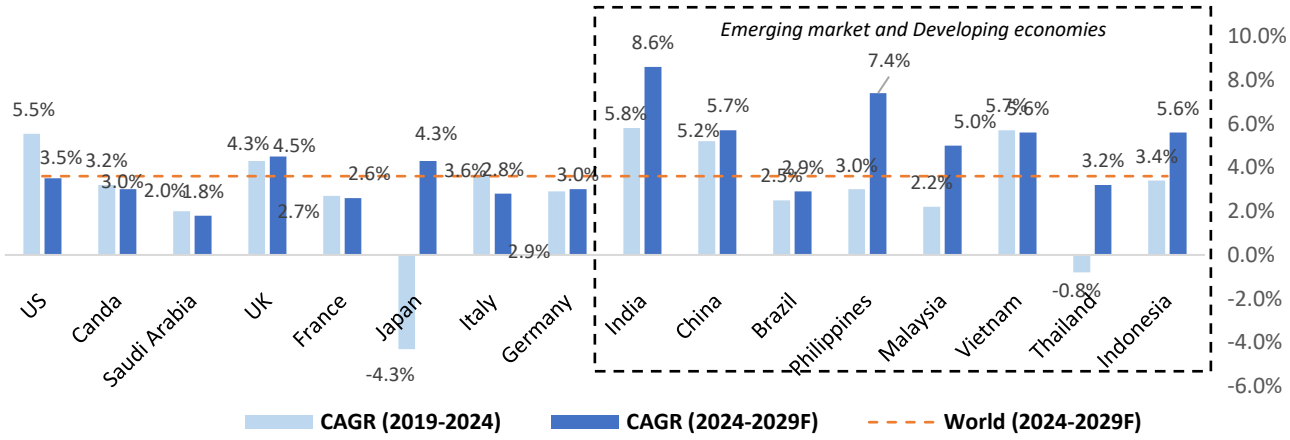
Source: World Economic Outlook-April 2025, Frost & Sullivan

1.1.2. GDP Per Capita

There are clear indications of potential economic growth based on the projected increase in GDP per capita until 2029, hinting at improved affordability owing to higher average incomes.

IMF's data indicates that the global GDP per capita is set to rise from USD 13,933 in 2024 to USD 16,605 in 2029 at a CAGR of 3.6%. The upward trend points to potential economic growth and, in combination with reduced inflation projections, serves as an indirect measure of increased purchasing power and potential economic prosperity. While advanced economies such as the US, Japan, Italy, and Germany are set to experience a slowdown in the GDP per capita growth, emerging Asian markets such as India and China are set for a growth wave, with India in particular set to grow at 8.6% CAGR between 2024 and 2029. Similarly, emerging markets in Southeast Asia, such as Vietnam, Indonesia, and the Philippines, are expected to witness a high GDP per capita growth of above 5.5% between 2024 and 2029.

Exhibit 1.6: GDP per Capita CAGR at Current Prices, Select Countries, 2019-2029F



Source: World Economic Outlook-April 2025, Frost & Sullivan

1.2. Contribution of manufacturing and healthcare in GDP growth and vice versa

The share of manufacturing in India's GDP is steadily increasing due to factors such as government initiatives (e.g., FDI, Make in India), availability of skilled labor supply, and other factors. The manufacturing sector's contribution to India's GDP was about 13% in FY 2023 and 2024. The Indian government aims to raise manufacturing's share of GDP through policies like the Production-Linked Incentive (PLI) scheme, National Manufacturing Policy, and creating a medical device manufacturing ecosystem through Medtech parks in the country and incentivizing the manufacturing of medical device products.

The Indian government's expenditure on health is growing at a 15.0% CAGR[2] between FY18 and FY24, while the healthcare expenditure as a percentage of GDP has been steadily increasing in recent years, with figures from the Economic Survey showing a rise from 1.6% in FY23 to 1.9% in FY24. The Health Ministry aims to increase this to 2.5% of GDP by FY25. The Indian healthcare sector was valued at USD 372.0 billion in 2023 and is projected to reach USD 638.0 billion by 2025 (CAGR of ~26.0% from 2023–2025), driven by increasing elderly population, improved affordability and accessibility of healthcare services, rise in non-communicable diseases, and increasing insurance penetration. Moreover, technology is playing an increasingly vital role in advancing healthcare by improving diagnostics, treatments, and patient care through AI, telemedicine, and wearable devices, ultimately leading to a more accessible, efficient, and personalized healthcare experience. The healthcare sector employs 7.5 million people

[2] Press Information Bureau (PIB)

(2024) and is expected to create 2.7–3.5 million new tech jobs by 2028 due to advancements in telemedicine and AI.[3] Government initiatives like Ayushman Bharat and digital health missions, combined with rising private investments, are poised to further boost the sector's contribution to GDP growth.

1.3. Growth Drivers for India's Healthcare Sector

India's unique demographic dividend presents a plethora of talent in the Science & Technology Engineering, Mathematics (STEM) field, infrastructure investment by the government, including commendatory reforms, and low cost of manufacturing are likely to present a compelling case for many pharmaceutical and medical devices companies to invest as their global base, thereby accelerating economic growth in the country.

1.3.1. Demographic Advantage

India's populous nature is rapidly turning into its biggest strength in the upcoming decade as its working-age population continues to rapidly increase from 50.2% in 2023 between the 25 to 64 age brackets to 51.7% by 2027. India's low-cost talent supply across the STEM field is a compelling investment prospect for global multinational pharmaceutical and medical device companies, which are heavily skill intensive. Leading global Pharmaceutical and MedTech companies are increasingly committing to building a strong presence in India. This is expected to create Lifescience hubs and jobs, leading to increased opportunities, more urbanization, and an increasingly affluent population, which in turn can drive demand for goods and services, further contributing to growth.

1.3.2. Government Reforms for the Manufacturing Sector

From economic to structural reforms, several of the Indian government's initiatives have bolstered investment and streamlined growth across several sectors, most notably pharmaceutical and medical device manufacturing.

- **Development of "Make in India" Programs, PLI Scheme, and Medical Device parks:** Under the current administration, the Indian government has implemented several favorable policies to promote manufacturing, such as the tariff on imports, Production-Linked Incentive (PLI) scheme, PM Gati Shakti- National Master Plan (NMP), and industrial development schemes in states with industrial backwardness. The reforms have been targeted towards increasing the impact of the manufacturing sector on the country's GDP as a part of the government's bold vision. The PLI scheme provides financial incentives to selected companies for the domestic manufacturing of medical devices. The Scheme for Promotion of Medical Device Parks is aimed at providing financial assistance to states for establishing common infrastructure facilities in medical device parks, with a total outlay of USD 47.8 million. Several government-backed Medical Device Parks are being developed across India to boost domestic manufacturing of medical devices, reduce costs, and improve access to affordable healthcare. These parks offer infrastructure and support for manufacturing, research, and development, aiming to transform India into a global hub for medical technology.

- **Foreign Direct Investment (FDI) policy:** There has been a keen focus by the Indian government on terms of implementation of favorable FDI policy reforms for pharmaceutical and medical device companies. The central government established the Medical Devices Rule to clearly differentiate between pharmaceutical and medical device companies to streamline the regulatory environment and promote investments. Further, the Union cabinet approved the amendment to FDI% for greenfield projects, allowing up to 100.0% FDI through the automatic route and 74.0% FDI through the automatic route for brownfield projects without the requirement of government approval[4].

[3] IBEF
[4] IBEF

- **Emergence of public insurance coverage and integration of public and private healthcare delivery sectors:** The awareness of the impact of healthcare on the country's growth is clearly reflected through IRDAI's (Insurance Regulatory and Development Authority of India) 2047 vision of insuring every citizen with life and health insurance cover by bringing together the public and private sector players. The imminent roll-out of the BIMA SUGAM, a revolutionary digital platform, will serve as a one-stop integrated digital insurance marketplace for regulated buying of insurance, policy reviews, and claims settlements, enabling health insurance penetration in rural India. The infrastructure built around the BIMA SUGAM integrated digital insurance marketplace platform will universalize and democratize insurance. Another example of strengthening the public insurance coverage is the government's Pradhan Mantri Jan Arogya Yojana (PM-JAY) scheme, which is focused on shifting the country's healthcare delivery model from a fragmented approach towards a need-based service. The central government's Ayushman Bharat scheme (PMJAY) covers a wide range of diseases, including cardiac conditions (e.g., stents, balloon angioplasty), cancer, neurosurgery, kidney transplants, burns, and congenital disorders. The increased insurance coverage and integration of public and private healthcare delivery sectors are set to create a greater demand for indigenously manufactured pharmaceuticals and medical devices.

2. Healthcare Landscape

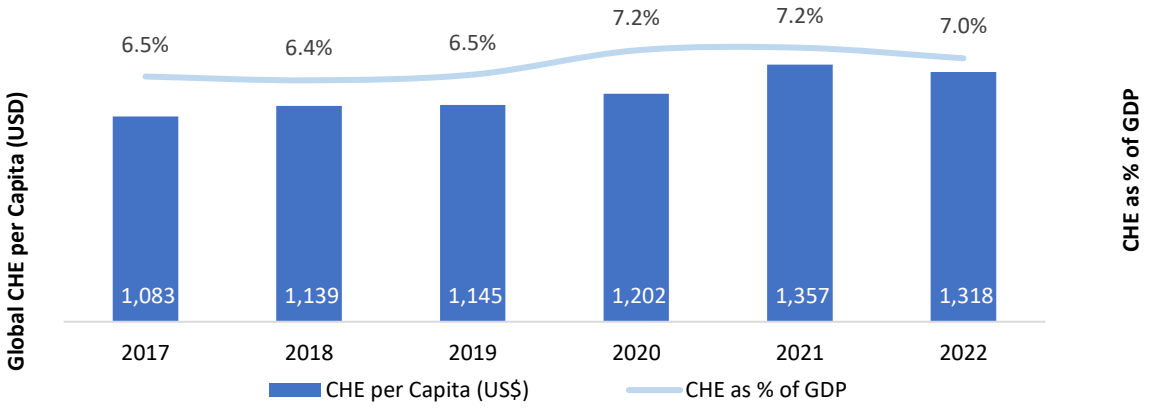
2.1. Global Current Healthcare Expenditure

The focus on healthcare has increased as levels of disposable income rise and awareness of health and wellbeing grows in the wake of the pandemic, resulting in a significant increase in discretionary spending on health.

Increased access to healthcare across the globe has come at a huge financial cost for a large part of the global population and is not limited to lower-income countries, with more than 20% of healthcare expenditures in the form of out-of-pocket expenses. Post-pandemic, economies continue to invest in strengthening the resilience of their healthcare systems for the long term and address the growing needs of the population in the short term. WHO data indicates a steady rise of per capita current healthcare expenditure globally at a 4.0% CAGR from USD 1,083 in 2017 to USD 1,318 in 2022, signifying increased health spending across the globe, while the increase in external aids, critical to low and lower-middle income countries, also continues to see a sharp increase, signifying a positive outlook towards overall health spending globally.

Exhibit 2.1: Global Current Healthcare Expenditure (CHE) : 2017 - 2022

CHE per Capita CAGR (2017-2022) = 4.0%



Source: WHO, Frost & Sullivan

2.2. Growth drivers for rising Healthcare Expenditure

Healthcare expenditure has been growing consistently and considerably for the last five decades, with an average increase of around 4.0% per year since 1970. The major drivers for rising healthcare expenditures are increased access to healthcare, prevalence of chronic diseases, precision medicine, and next-generation diagnostics.

Increased access to healthcare: Increasing penetration of health insurance, rapid urbanization and spending capacity, and technological advancements such as remote patient monitoring and telehealth have improved healthcare access, particularly post-pandemic. While remote monitoring and telehealth have the potential to reduce costs by enabling continuous patient monitoring and early intervention, they also introduce new expenses related to technology infrastructure and data management.

Prevalence of chronic diseases: Chronic diseases are expected to cost an estimated USD 47.0 trillion by 2030 and are the leading cause of death worldwide, according to the WHO. The burden of chronic diseases such as diabetes, heart disease, cancer, and respiratory diseases is increasing across the globe. The primary factors contributing to the increased burden are an ageing population, increased life expectancy, urbanization, imbalanced diets, poor air quality, and lifestyle changes.[5] Among deaths from non-communicable diseases in 2021, cardiovascular disease (CVD) had the highest share (45%), and it accounts for one-third of all global deaths. About 80% of CVD deaths take place in low- and middle-income countries, where raised blood pressure happens to be amongst the most important risk factors for CVDs.

Innovation in Medical Devices: Medical device innovation often involves the development of new mechanical principles, materials, or software that improve an existing device or enable a new procedure. Patents for medical devices are essential for providing a competitive advantage and a return on investment. The innovation cycle in medical devices is often characterized by a series of incremental improvements. A company may introduce a new generation of a device every few years. The development timeline for a medical device can range as high as 7 years or more for a high-risk implantable device. Due to the R&D intensive nature of the industry, the costs are often passed on to the payers and/or patients, leading to an increase in healthcare expenditure. The use of clinical and molecular diagnostics at increasing frequencies has also led to an increase in healthcare expenditure. Rapid adoption of new clinical diagnostic technologies such as molecular diagnostics, next-generation sequencing, and biomapping is providing new insights into disease pathways, driving greater personalization of treatment regimes. Advances in medical device areas such as robotic surgery, implants, and advanced imaging systems, whilst successful in improving patient outcomes, carry a significant cost factor with them. Further, growing emphasis on personalized medicine, also often referred to as precision medicine, represents a significant shift in how healthcare is approached by tailoring medical treatment to the individual characteristics of each patient. While promising more effective treatments, personalized medicine often requires advanced genetic testing and data analysis, which can be expensive. The complexity and training required for implementation also add to healthcare costs.

Global ageing population: Globally, people are living longer. Most people nowadays can anticipate living well into their sixties and beyond. Both the number and percentage of older people in the population are rising in every nation on the planet. One in six individuals on the planet will be 60 years of age or older by 2030. The number of individuals in the world who are 60 years of age or older is expected to double (to 2.1 billion) by 2050, with most of them located in low- and middle-income countries. It is anticipated that between 2020 and 2050, the number of people 80 years of age or older will triple, reaching 426 million.[6] China, India, the US, Japan, and Russia are the top 5 countries with the largest number of older adults in 2023. In India, the population of over 65 years of age has increased from 5% of the total population in 2013 to 7% of the total population in 2023.[7] The impact of cardiovascular diseases has always

[5] United Nations Population Division, World Bank
[6] WHO, Ageing and Health
[7] Population Reference Bureau, United Nations Population Division, World Population Prospects 2019

been significant among the population aged 65 and older, and with better healthcare access and increased life expectancy, the patient population is set to expand significantly.

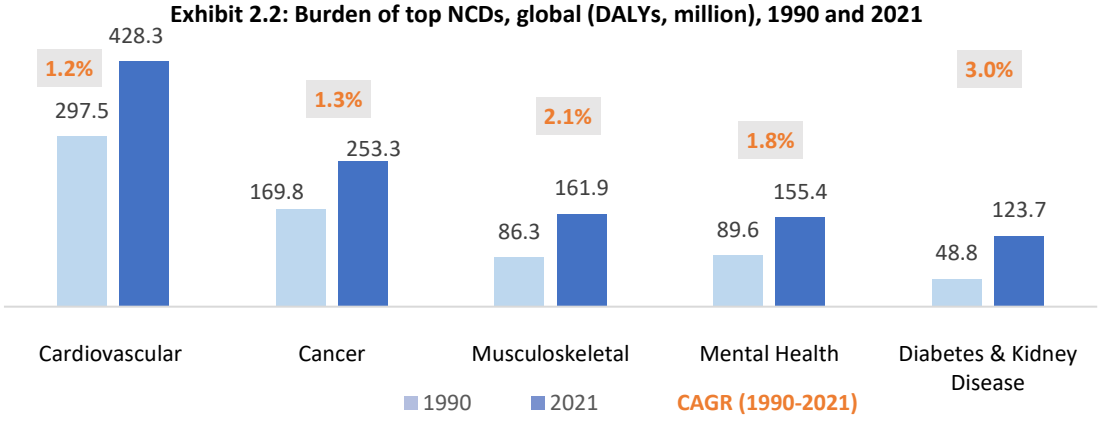
Growing awareness of healthcare: A growing awareness among individuals regarding their health and well-being is increasingly acting as a significant growth driver for healthcare spending. As people become more informed about preventive care, early disease detection, and the availability of advanced treatments, they are more proactive in seeking medical attention and investing in health-related services. This heightened health consciousness, fueled by access to information and a desire for a better quality of life, leads to increased demand for regular check-ups, screenings, specialized consultations, and elective procedures. Furthermore, a greater understanding of chronic conditions and their long-term management often results in sustained engagement with healthcare providers and adherence to treatment plans, contributing to higher overall expenditure. This shift towards a more health-conscious populace, eager to leverage healthcare for both preventive and curative purposes, fundamentally expands the market for healthcare services and products.

Rising Non-Communicable Disease Burden

The total global disease burden from non-communicable diseases (NCDs), measured in DALYs (Disability-Adjusted Life Years)[8] Per year has increased from 1,150.0 million in 1990 to 1,700.0 million in 2021. The top 5 NCDs as per DALYs are Cardiovascular disease, Cancer, Mental disorder, Musculoskeletal disorders, and Diabetes and Kidney disease.

NCDs account for most deaths in most Asian countries. In the Southeast Asia Region alone, they are responsible for

Exhibit 2.2: Burden of top NCDs, global (DALYs, million), 1990 and 2021



Source: Our World in Data, Frost & Sullivan

an estimated 8.5 million deaths annually, representing a significant proportion of all deaths. This burden is also reflected in the high number of disability-adjusted life years (DALYs) lost due to these conditions. A concerning feature of the NCD burden in Asia is the high rate of premature deaths (before the age of 70). This is particularly evident in low- and middle-income countries within the region, where a larger proportion of NCD-related deaths occur in younger individuals compared to high-income nations. Factors such as rapid urbanization, globalization, changing lifestyles, and aging populations are contributing to the increasing prevalence of NCDs across Asia.

The burden of NCDs for most of the major economies is increasing due to factors such as changes in lifestyle and dietary habits and increasing detection of metabolic disorders. The NCD burden in India is among the highest in the world, and it has increased by more than 50.0% from 1990 to 2021 (157.5 million DALYs in 1990 to 283.6 million DALYs in 2021) due to the longevity and increasing prevalence of cardiovascular and other disorders. The burden of most NCDs, such as Cardiovascular, Neurological, Cancer, and Musculoskeletal diseases, has nearly doubled from

[8] DALYs are used to measure total burden of disease - both from years of life lost and years lived with a disability. One DALY equals one lost year of healthy life.

1990 to 2021. In 2021, CVD accounted for a substantial disease burden in India, with significant numbers of deaths and disability-adjusted life years (DALYs). Specifically, CVD was responsible for 2.9 million deaths, representing 14.9% of global CVD deaths. NCDs are the number one cause of death and disability worldwide and disproportionally affect people in low and middle-income countries (LMICs) across Europe, Asia, and Latin America regions, where three out of four cases occur. Noncommunicable diseases (NCDs), including heart disease, stroke, cancer, diabetes, and chronic lung disease, are collectively responsible for 74% of all deaths worldwide.

Table 2.1: Burden of NCDs as per DALY, Select developed and emerging countries, 1990 and 2021

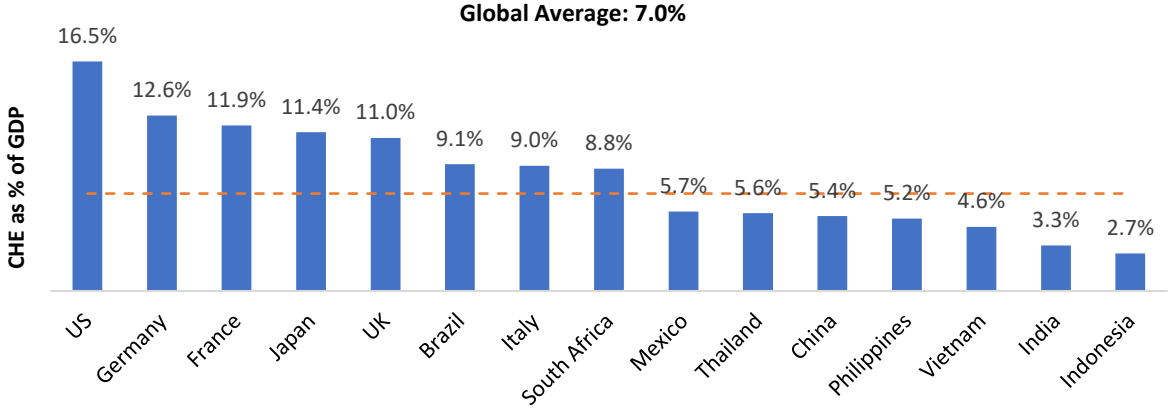
Country	1990 (DALY, in million)	2021 (DALY, in million)
India	**157.5**	**283.6**
US	66.1	98.0
Brazil	28.2	48.6
Germany	25.3	24.8
Mexico	14.3	28.5
UK	17.4	17.0
Italy	15.9	16.1
Philippines	10.2	21.5
Vietnam	10.5	19.9
France	14.5	15.8
Thailand	9.4	16.6
Spain	9.8	11.2
Canada	6.1	8.8
South Africa	6.0	11.6
Australia	3.9	5.5
Saudi Arabia	2.8	6.7

Source: Our World in Data, Frost & Sullivan

2.3. Current Healthcare Expenditure across Key Countries

In the developed economies, many countries have high Current Health Expenditure (CHE) as % of the country's GDP. For example, the United States, with its well-developed need-based healthcare approach, has the highest CHE as % of GDP of the country, 16.5%, %, and countries such as Germany, France, Japan, and the UK have a high percentage at 12.6%, 11.9%, 11.4% and 11.0% respectively. The high CHE as % of GDP is due to higher healthcare spending in these economies, in addition to advances in medical and device innovation, which also stems from these regions. The emerging economies, particularly in the low-and middle-income countries, receive external aid to supplement their low CHE. But a key element across the globe in terms of healthcare expenditure is the investment in strengthening the resilience of healthcare services post the COVID-19 pandemic.

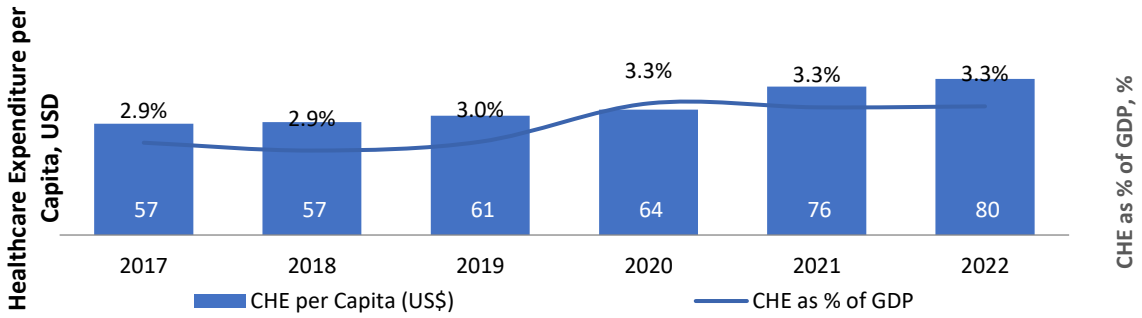
Exhibit 2.3: Current Healthcare Expenditure as % GDP by Country: 2022
Global Average: 7.0%



Source: WHO, Frost & Sullivan

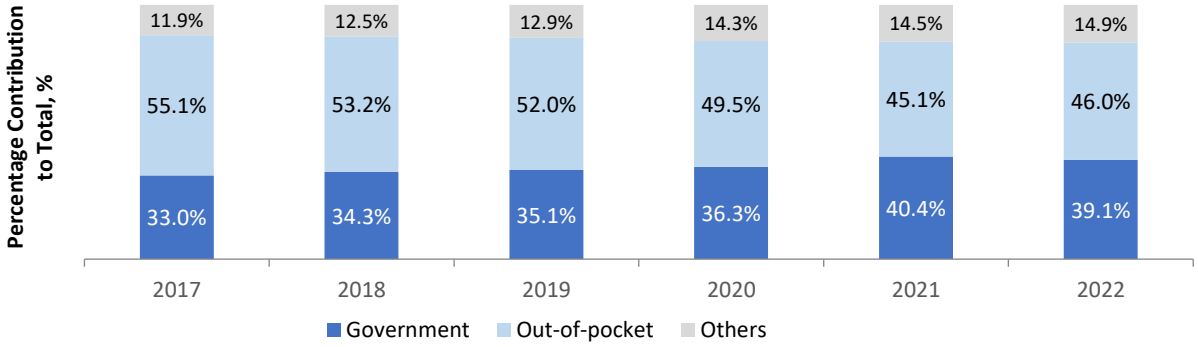
While the global average of CHE is 7.0%, India's CHE is one of the lowest in the world, at 3.3%. Indian healthcare is a complex system that has traditionally been tethered between value and need-based care, as both the public and private sectors play equally critical roles. The healthcare system is also heavily reliant on out-of-pocket payments, especially in the private sector. The current Indian government initiatives to increase public coverage have played a big role in increasing the current healthcare expenditure as % of GDP. The Indian government's investments in reforms such as Pradhan Mantri Jan Arogya Yojana, Ayushman Bharat, and BIMA platforms aim to increase coverage and healthcare access. India's current healthcare expenditure as % of its GDP (includes government and private sources) has increased from 2.9% in 2017 to 3.3% in 2022.

Exhibit 2.4: India's Current Healthcare Expenditure at Current Prices, 2014-2022



Source: WHO, Frost & Sullivan

Exhibit 2.5: India's CHE by Financing Source: 2017-2022



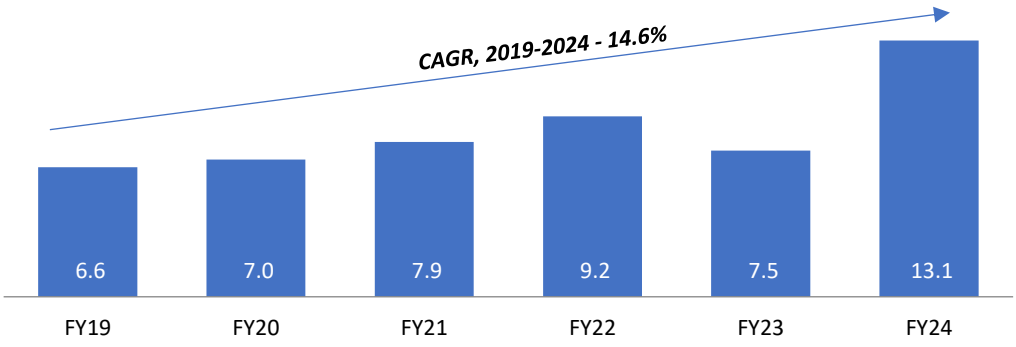
Source: WHO, Frost & Sullivan

India is witnessing rising insurance adoption and increasing healthcare coverage from the Government.

India is witnessing increasing healthcare financing from the government. A pivotal government initiative, the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PMJAY), provides comprehensive hospitalization coverage to approximately 700 million individuals, or the lower 50.0% of the population. Only about 37% of the total population (514 million people) are covered by health insurance schemes, leaving a significant portion uninsured.[9] Government expenditure as a percentage of healthcare expenditure in India has grown from 33.0% in 2017 to 39.1% in 2022. While India's Out-of-Pocket (OOP) healthcare spending has decreased from 55.1% in 2017 to 46.0% in 2022 due to higher insurance penetration, it is notably high. Furthermore, India's OOP burden surpasses that of other emerging markets and developing economies such as China (34%), Vietnam (40%), Indonesia (33%), Brazil (27%), and Mexico (39%), and significantly exceeds the World Health Organization's recommended range of 15.0% to 20.0%[10].

The adoption of health insurance is increasing in India, where the gross premium underwritten has increased from USD 6.6 billion in FY 2019 to USD 13.1 billion in 2024 at a high CAGR of 14.6%. Factors such as increased awareness of health, prevention of catastrophic health expenditure by households, increase in medical costs, increased acceptance of health insurance by hospitals, and increase in household income are key drivers for the adoption of health insurance.

Exhibit 2.6: Health insurance premium collection (USD Billion), 2019-2024



Source: IBEF, Frost & Sullivan

Demand for Hospital Beds

[9] Forbes
[10] WHO Report

Globally, there has been a marked increase in the demand for hospital beds due to the increasing burden of diseases, healthcare expenditure, and adoption of healthcare services. This growth in demand is particularly notable in emerging markets, where governments and private investors are investing heavily in healthcare infrastructure to meet the rising demand for medical services and address the shortage of beds. Moreover, in many emerging economies, there is a significant disparity between the number of available beds and the number of beds necessary as per WHO standards. For instance, India has around 1.6 beds (government and private hospital beds) per 1,000 people, which is only about half of the recommended beds by WHO (3.0 beds per 1000).[11] Developed countries are also expanding their hospital networks, focusing on specialized care facilities to address the growing demand for healthcare services. Emerging markets such as India are witnessing a higher growth in hospital beds compared to global rates, improving the capacity of hospitals for inpatient uptake. Increase in hospital beds and inpatient admissions, driven by the rising incidence of diseases and physical disabilities, is expected to propel the demand for medical devices.

Table 2.2. Comparison of bed density in select countries

Country	Beds/1000 people	Gap as per the WHO bed requirement/1000 people
India	**1.6**	**1.4**
US	2.7	0.3
China	5.0	(2.0)
Saudi Arabia	2.1	0.9
France	6.0	(3.0)
United Kingdom	2.4	(0.6)
Germany	7.8	(4.8)
Vietnam	2.5	0.5
Thailand	2.3	0.7
Indonesia	1.4	1.6
South Korea	12.8	(9.8)
Brazil	2.5	0.5
Mexico	1.0	2.0
Poland	6.1	(3.1)
Italy	3.2	(0.2)
Spain	2.9	0.1

3. Global MedTech Market

Medical technology (MedTech), defined broadly, refers to instruments, consumables, apparatus, machines, implants, or other products used to diagnose, cure, mitigate, treat, or prevent disease, without being absorbed or metabolized by the body.[12]. It encompasses various products, including medical devices, diagnostic tools, and capital equipment used across healthcare settings such as homes, clinics, hospitals, and laboratories. This industry produces an enormous variety of products, ranging from common medical supplies such as surgical gloves and syringes to reagents and equipment used in clinical diagnostics to advanced imaging equipment and implantable devices like

[11] WHO sources
[12] AdvaMed: Medical Device Industry Facts

cardiac defibrillators and artificial joints. Currently, there are approximately 2.0 million types of medical devices available in the global market, categorized into over 7,000 generic device groups.[13]

3.1. MedTech Regulatory Environment

Medtech companies benefit from a diversified product portfolio spanning different risk classes, enabling them to navigate regulatory challenges while optimizing market access and revenue streams. Strategic alignment with evolving global regulations is paramount to sustaining competitiveness in the dynamic medical device industry.

Given the diversity of MedTech products, regulatory agencies worldwide classify them based on risk levels to ensure safety and efficacy. However, classification frameworks and approval processes vary significantly across regions, influencing market access, innovation timelines, and compliance costs for MedTech companies.

The classification of medical devices has evolved as regulatory agencies recognized the need for structured, risk-based oversight. In one of the most stringent markets, in the United States, the Food and Drug Administration (FDA) formalized its classification system with the 1976 Medical Device Amendments, introducing three classes based on risk levels.[14]. Europe initially operated under the Medical Device Directive (MDD) before transitioning to the current Medical Device Regulation (MDR), which has a four-tier classification system. Japan's Pharmaceuticals and Medical Devices Agency (PMDA) adopted a similar four-class framework.

India's regulatory landscape was historically fragmented, with limited oversight, until the introduction of the Medical Device Rules in 2017 under the Central Drugs Standard Control Organization (CDSCO), which established a structured classification system aligned with global best practices. Other emerging markets, such as Turkey (MDR) and China (NMPA), while initially having less stringent regulatory frameworks, have progressively aligned with international standards to enhance compliance and global market access.

While developed markets prioritize safety through rigorous regulatory oversight, emerging markets seek to balance safety with expedited approval pathways. As a result, India's evolving regulatory framework aligns with international best practices yet retains distinct approval mechanisms that shape market entry strategies.

Medical device classification and approval processes present inherent complexities, particularly for high-risk devices. Medical devices, diagnostics, and capital equipment are categorized into different classes based on their potential risk to patients. Low-risk devices include items such as surgical gloves and blood pressure monitors, whereas high-risk devices encompass implantable pacemakers, artificial heart valves, and advanced imaging systems.

The classification frameworks of major regulatory devices are structured as follows:

Table 3.1: Select Regulatory agencies and classification of Medical Devices

Country	Classification	Definition by Class	Approval Pathways
USA (FDA)	Class I, II, III	Low, moderate, and high risk	Class I: General controls; Class II: 510(k) submission[15]; Class III: Premarket Approval (PMA)
European Union (MDR)	Class I, IIa, IIb, III	Low to highest risk	CE marking via notified bodies, clinical evidence required for higher classes
China (NMPA)	Class I, II, III	Low to high-risk	Local clinical trials are required for Class II and III unless prior approvals exist in major markets. For devices that pose high risks to human health, NMPA approval is particularly stringent, and local trials are more likely to be mandated.

[13] WHO: Medical Devices
[14] FDA: 510K and PMA Approvals
[15] Under the 510(k) pathway, a medical device manufacturer submits a premarket notification to the FDA, demonstrating that the device is "substantially equivalent" to a device that has already been cleared by the FDA and is in commercial distribution.

India (CDSCO)	Class A, B, C, D	Low to highest risk	Class A: Self-certification; Class B: Notified body certification; Class C & D: CDSCO approval with clinical data for novel devices

Source: Frost & Sullivan

- Low-risk devices, such as surgical instruments, thermometers, and basic diagnostic tools, often undergo simplified approval pathways. In the US, many Class I devices are exempt from premarket notification, requiring only adherence to general controls for quality and labeling compliance. Similarly, in India, Class A devices require self-certification, while Class B devices undergo third-party certification. However, as risk levels escalate, regulatory complexity increases substantially.
- Class III devices or Class D, which include implantable pacemakers, cardiac stents, drug-coated balloons, artificial heart valves, and sophisticated imaging systems—face the most stringent regulatory scrutiny and are used in life-saving procedures performed by specialists such as cardiologists. The approval process for these high-risk devices demands extensive preclinical and clinical data, post-market surveillance commitments, and strict manufacturing controls. In developed markets, approval pathways include the FDA's Premarket Approval (PMA) process, which entails comprehensive clinical trials and stringent safety benchmarks, as well as the European MDR's requirement for robust clinical evidence. Conversely, emerging markets such as India and China offer expedited approvals for devices already recognized by regulators in the US and EU.

Regulatory complexity significantly influences go-to-market strategies for MedTech companies, necessitating a well-defined approach to navigating diverse approval pathways. Companies must develop comprehensive regulatory strategies that account for region-specific compliance requirements, separate clinical trial mandates, and evolving regulatory frameworks. Diversification across different classes of devices mitigates regulatory risks and revenue fluctuations.

Maintaining a balanced portfolio that includes both low-risk and high-risk devices enables companies to generate consistent cash flow from rapidly approved products while investing in long-term, high-reward innovations. MedTech companies need to carefully assess each region's regulatory landscape, weighing the benefits of expedited approvals in emerging markets against the predictability and stringent safety requirements in developed markets to get strong market access. Cost and resource allocation are crucial, as high-risk devices necessitate substantial R&D investments, specialized regulatory expertise, and extended approval timelines.

In India, if a medical device has a predicate device (a similar device already approved and marketed), it's more likely that the regulatory authority (CDSCO) will accept foreign clinical data. Devices that have been marketed for a certain period (e.g., 2 years) in countries like Australia, Canada, Japan, Europe, or the US are likely to have their foreign trial data accepted by the CDSCO. Even with accepted foreign data, the CDSCO may require post-marketing surveillance or investigations based on expert committee reviews. If a device is new and does not have a predicate device or if there are significant differences in the clinical environment or population between where the foreign data was collected and India, local clinical investigation or bridging studies must be conducted. If bridging studies are required, this can add to the development timeline, as these studies can take time to plan, conduct, and analyze.

Challenges in regulatory compliance, manufacturing, and market access differ by risk classification, influencing the ability of companies to scale operations efficiently:

Table 3.2: Risk-based classification of Medical Devices and Regulatory challenges

Class	Regulatory Challenges	Example	Manufacturing Challenges	Market Access Challenges
Low risk (Class I/A)	Varied exemptions and compliance requirements across regions	Stethoscopes, Thermometers, Surgical masks	Standardized processes, but competitive cost pressures	Rapid market entry, but price sensitivity
Low-Moderate Risk (Class II/ IIa/ B)	Special controls and variable premarket requirements	Blood pressure monitors, Hearing aids, Nebulizers	Higher quality assurance costs and design controls	Greater differentiation is needed for competitive positioning

Moderate-High Risk (Class II/ IIb/ C)	Extensive clinical data requirements, prolonged approval timelines	X-Ray Machines, Defibrillators, Hemodialysis machines, Cardiac Monitor	Complex manufacturing processes, stringent validation needs	Higher market entry barriers, reimbursement complexities
Highest risk (Class III/ D)	Rigorous regulatory scrutiny, mandatory clinical trials, and post-market surveillance	Stents, Heart Valves, Cardiac Pacemakers, Orthopedic Implants	Advanced R&D investments, sophisticated manufacturing infrastructure	Limited market size, high commercialization costs

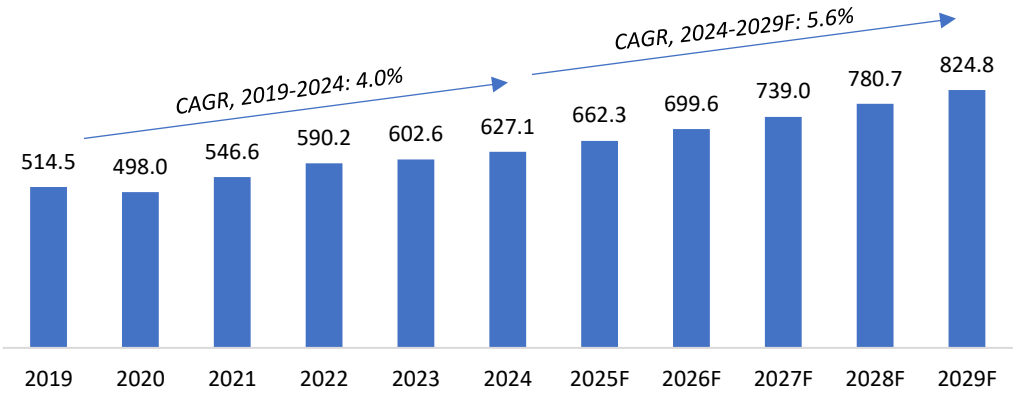
Source: Frost & Sullivan

3.2. Global MedTech Market Size and Forecast

The MedTech industry is poised for sustained and 5.6% growth, underpinned by continuous innovation, regulatory evolution, and shifting demographic trends.

The global MedTech industry has undergone a significant transformation over the past decade, driven by rapid advancements in technology, rampant consolidation, and value chain compression. In 2024, the industry is valued at approximately USD 627.1 billion, having expanded at a CAGR of 4.0% from 2019 to 2024. With continued innovation, increasing healthcare expenditures, improving infrastructure, and rising demand for early disease detection and personalized treatment, the market is forecasted to reach 824.8 billion by 2029, reflecting a projected CAGR of 5.6% during the 2024–2029 period.

Exhibit 3.1: Global MedTech Market (USD Billion), 2019-2029F



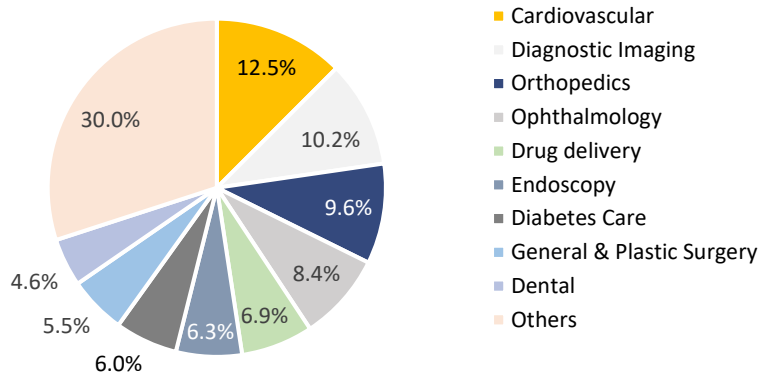
Source: Frost & Sullivan

For the purpose of this study, the MedTech market has been broadly categorized into two key subsegments: medical devices and clinical diagnostics plus laboratory solutions.

- Medical devices, encompassing products such as cardiovascular devices, imaging systems, orthopedic devices, surgical instruments, and patient monitoring solutions, represent the largest share of the market at 82.6% in 2024, with a market value of USD 518.0 billion. Increased adoption of digital health solutions, artificial intelligence-driven diagnostics, and robotic-assisted surgeries have accelerated growth in this segment, which is projected to reach USD 667.4 billion by 2029, growing at a CAGR of 5.2%.

- Among the medical device product segments, Cardiovascular devices account for the highest market share (12.5%), followed by other segments such as Diagnostic imaging (10.2%), Orthopedics (9.6%), Ophthalmology (8.4%), Drug delivery devices (6.9%), and Endoscopy devices (6.3%). The increasing prevalence of cardiovascular diseases has boosted the use of medical devices in hospitals and clinics worldwide. Cardiovascular diseases like coronary artery disease, hypertension, heart failure, and arrhythmias are increasing globally and contribute to a major share of mortality worldwide.

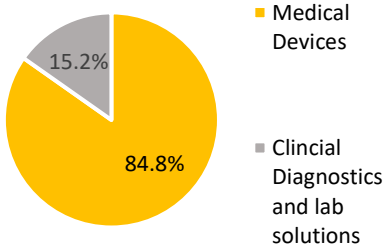
Exhibit 3.2: Global Medical Device market, share by segments, 2024



Source: Frost & Sullivan

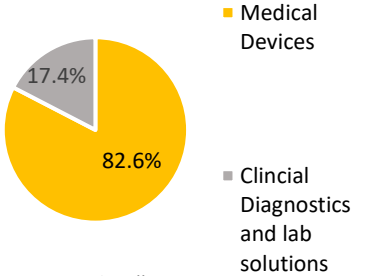
- The clinical diagnostics segment comprises mainly in-vitro diagnostics tests such as clinical chemistry, immunochemistry, hematology, microbiology, and molecular diagnostics, which are conducted in blood and tissue samples. The segment has a share of 17.4% in the MedTech market. The clinical diagnostics sector has also witnessed substantial expansion, with its market size growing from USD 78.4 billion in 2019 to USD 109.1 billion in 2024. The growth of clinical diagnostics was accelerated by the COVID-19 pandemic, and it is being driven by heightened awareness of early disease detection, rising incidences of chronic diseases, and the growing accessibility of point-of-care testing methods, including molecular diagnostics. As scientific lab solutions for academic and industry research continue to evolve with advancements in diagnostics using genomics, biomarker research, and high-throughput screening technologies, the segment is expected to see high growth potential. Looking ahead, the segment is expected to sustain its momentum, reaching USD 109.3 billion by 2029 at a projected CAGR of 7.4%, significantly higher than the medical device market.

Exhibit 3.3A: MedTech market, share by segments, 2019



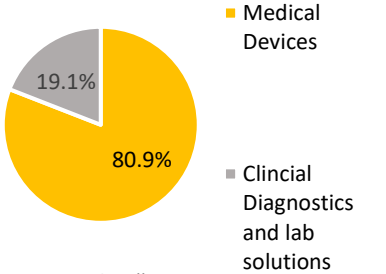
Source: Frost & Sullivan

Exhibit 3.3B: MedTech market, share by segments, 2024



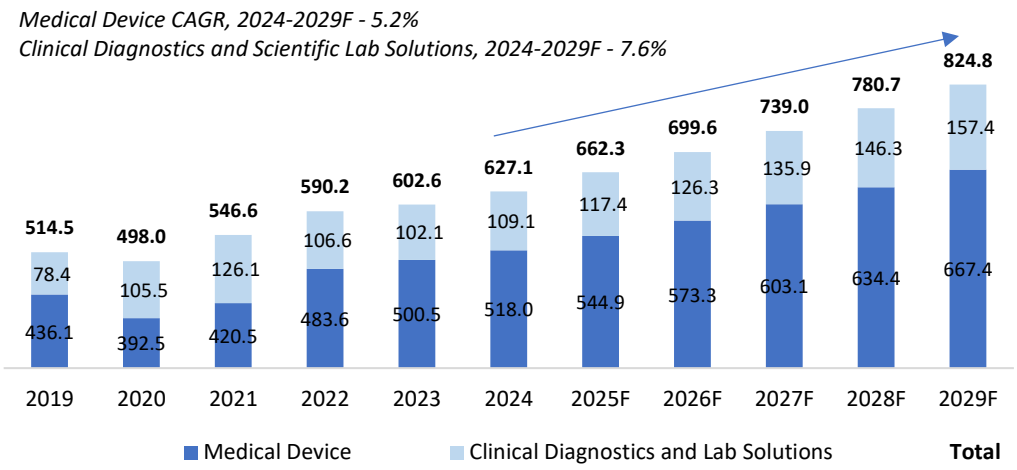
Source: Frost & Sullivan

Exhibit 3.3C: MedTech market, share by segments, 2029F



Source: Frost & Sullivan

Exhibit 3.4: Global MedTech Market by segments (USD Billion), 2019-2029F



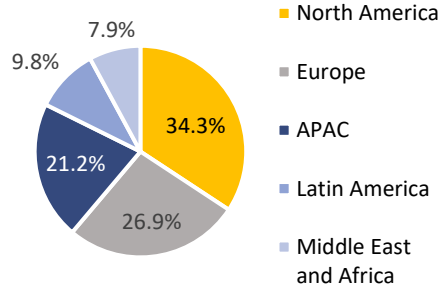
Source: Frost & Sullivan

3.3. Global MedTech Market by Geographies

While mature markets will continue to drive revenue through premium technologies and high-value care, emerging economies will increasingly shape the global landscape, offering lucrative opportunities for MedTech companies seeking to expand their footprint.

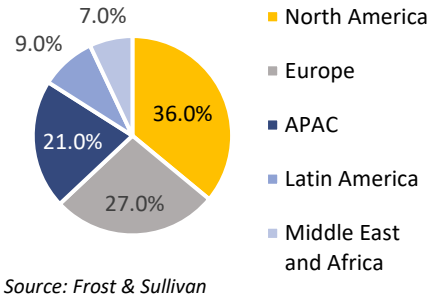
The North America MedTech market is valued at approximately USD 225.7 billion in 2024, with the US holding the majority share in the region. The European market is valued at USD 169.3 billion in 2024. Both regions are expected to have a lower growth rate (CAGR of 5.2%) in the forecast period between 2024 and 2029 compared to emerging market regions of APAC and Latin America.

Exhibit 3.5A: MedTech market, revenue share by region, 2019



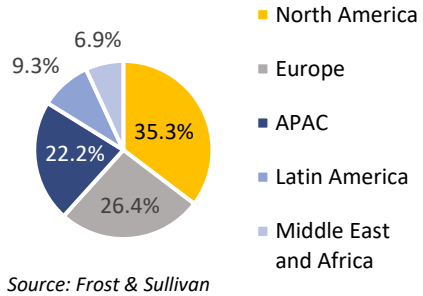
Source: Frost & Sullivan

Exhibit 3.5A: MedTech market, revenue share by region, 2024



Source: Frost & Sullivan

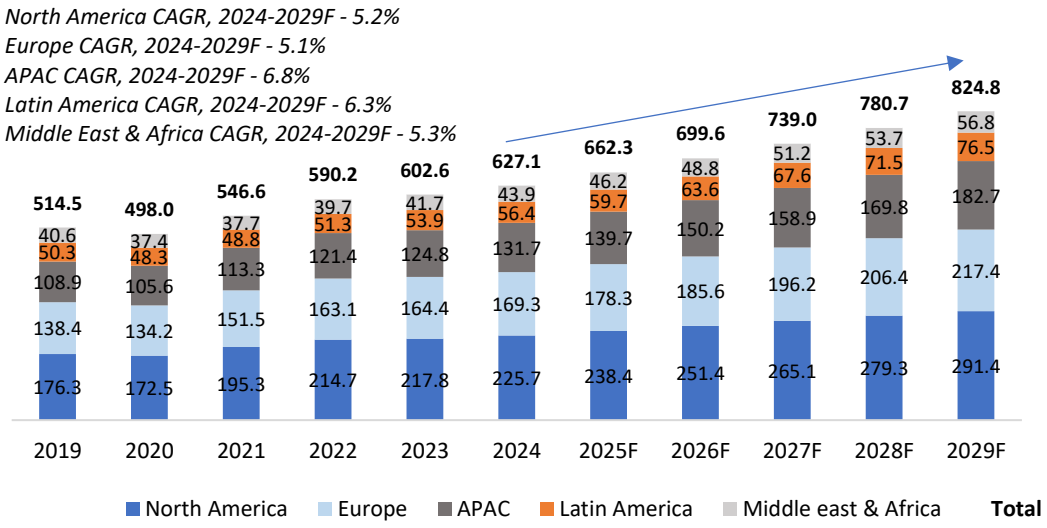
Exhibit 3.5A: MedTech revenue market, share by region, 2029F



Source: Frost & Sullivan

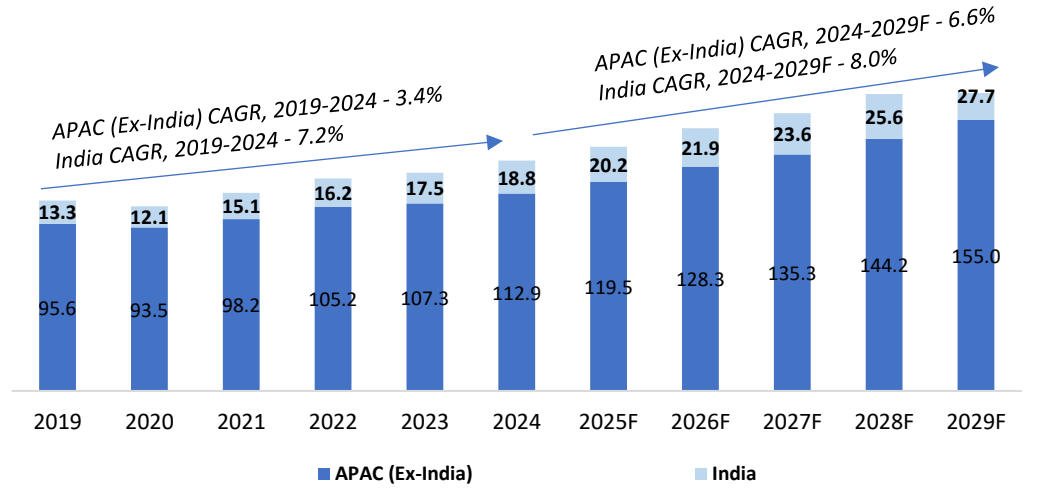
Further, other regions comprising Latin America, the Middle East, and Africa present immense opportunities due to increased government spending, the rising demand for cost-effective medical technologies, and improved accessibility and affordability of healthcare services. The Latin America MedTech market was valued at USD 56.4 billion in 2024 and is expected to reach USD 76.5 billion in 2029, growing at a CAGR of 6.3%. Similarly, the Middle East & Africa market was valued at USD 43.9 billion in 2024 and is expected to reach USD 56.8 billion in 2029, growing at a CAGR of 5.3%. With an estimated market size of USD 100.3 billion in 2024, the region is experiencing a robust CAGR of 5.9%, projected to reach USD 133.3 billion by 2029.

Exhibit 3.6: Global MedTech Market by Geographies (USD Billion), 2019-2029F



Source: Frost & Sullivan

Exhibit 3.6: APAC (Ex-India) and India MedTech Market (USD Billion), 2019-2029F



Source: Frost & Sullivan

Notably, the highest growth is witnessed in the emerging markets of Asia-Pacific (APAC) and India, collectively expected to outpace developed regions in the coming years. APAC, currently valued at USD 131.7 billion, is expanding at an impressive CAGR of 6.8%, set to reach USD 182.7 billion by 2029. India has grown at a higher rate

(7.2%) in the historical period compared to APAC, and its growth in the forecast period (8.0%) is expected to surpass APAC's growth. Commensurately, India's share in the APAC region is expected to grow from 12.2% in 2019 to 15.2% in 2029, fueled by government initiatives, a burgeoning middle class, and rising private sector investments in healthcare infrastructure.

Table 3.3: APAC and India MedTech Market

Region	2019			2029F		
	Revenue (USD Billion)	Global Share (%)	Share of APAC	2029F Revenue (USD Billion)	Global Share (%)	Share of APAC
APAC	108.9	21.2%	-	182.7	22.1%	-
India	**13.3**	**2.6%**	**12.2%**	**27.7**	**3.4%**	**15.2%**

Source: Frost & Sullivan

3.4. Growth Drivers of the MedTech Market

The MedTech industry is on an upward trajectory, shaped by technological progress, evolving patient expectations, and the growing need for efficient healthcare solutions worldwide.

- **Shift in consumer demand and decentralization of care delivery:** Healthcare delivery is no longer confined to hospitals, with a significant shift toward outpatient facilities, day-care surgery centers, retail clinics, and home-based care. The decentralization of care is improving care access to patients, increasing the demand for medical devices. Moreover, it is reshaping the MedTech industry by increasing the need for portable, user-friendly devices, fostering innovation in remote monitoring and AI integration, and emphasizing value-based healthcare. The demand for solutions such as remote patient monitoring devices, telemedicine-integrated diagnostics, and self-administered therapeutic devices to support decentralized care delivery is surging. This has led to growth in a new portfolio of devices such as portable imaging systems, point-of-care testing kits, and smart wearables embedded with biosensors, as well as increased consumption of devices.
- **Rising burden of chronic diseases:** The global prevalence of chronic diseases continues to escalate, driving demand for advanced medical technologies. For example, the number of people with diabetes in 2024 was close to USD 830 million, which is expected to reach USD 1.3 billion by 2050[16] , thus fueling demand for continuous glucose monitors, insulin pumps, and AI-assisted metabolic health platforms. Similarly, the rise in neurodegenerative disorders, including Alzheimer's and Parkinson's, is prompting innovation in implantable neuromodulation devices and early detection tests.
- **Increasing Healthcare spending and diversified funding support:** Global healthcare expenditure is projected to rise from USD 9.2 trillion[17] (8.3% of global GDP) in 2024 to USD 11.0 trillion (8.0% of global GDP)[18] in 2030, enabling greater adoption of cutting-edge MedTech solutions. The increasing participation of private equity and institutional investors in high-value medical equipment, such as cardiovascular therapies, next-generation diagnostics, robotic-assisted surgical systems, and precision oncology platforms, is accelerating market growth. Public-private partnerships in emerging markets are also facilitating the deployment of digital health infrastructure, improving access to diagnostics and treatment.
- **Rapid development and Integration of advanced technologies:** Technological advancements continue to redefine the MedTech landscape, with next-generation molecular diagnostics, bioabsorbable stents, and high-throughput laboratory automation leading innovation. Technologies such as minimally invasive cardiac

[16] WHO: Diabetes
[17] Institute of Health Metrics and Evaluation
[18] Global Health Journal

interventional and structural heart procedures, with advancements in transcatheter valve technologies, and novel diagnostic testing solutions are further revolutionizing patient care.

- **Growing R&D investments:** MedTech companies are allocating an increasing percentage of their revenue to R&D, with global R&D spending expected to reach approximately USD 39.0 billion in 2024 from USD 26.4 billion in 2022, growing at a CAGR of 21.5%.[19] Companies are focusing on breakthrough innovations such as new cardiac interventional devices (e.g., polymer-free and biodegradable stents), transcatheter valve replacements, Next-generation sequencing (NGS), and other molecular diagnostics and point-of-care technologies in clinical diagnostics, bioelectronic medicine, and next-generation neurostimulation systems. Increased venture capital and government funding in precision medicine, drug-device combinations, and hybrid surgical technologies are accelerating product pipelines and enhancing treatment efficacy. Asia-Pacific is experiencing rapid growth in R&D investment for the development of MedTech solutions with a focus on developing cost-effective solutions to meet the increasing demand from growing patient populations. For example, MedTech companies from India are increasing their R&D investments to develop cost-effective novel solutions to meet the varied needs of clinicians and patients, both in India and increasingly overseas.
- **Regulatory advancements supporting innovation and streamlined operations:** Evolving regulatory landscapes are shaping the global MedTech industry, with device companies the emerging markets like India and China producing quality products at lower costs as well as expanding into global markets. The FDA's streamlined approval pathways for breakthrough devices and Europe's MDR framework are fostering innovation in cardiovascular, neurology, and diabetes management technologies and enabling companies from emerging markets to compete with established MNCs. Further, China's simplified registration process and India's production-linked incentive (PLI) schemes are encouraging international MedTech firms to establish local manufacturing, improving accessibility and affordability. National Medical Device Policy, introduced in May 2023, aims to support the sector's growth through simplified regulations and creating an enabling infrastructure, R&D, and innovation ecosystem.

3.5. Trends in the Global MedTech Market

3.5.1. Growing Presence of Indian Companies in the Market

Indian MedTech companies are rapidly expanding their footprint in global markets, driven by indigenous innovation, a growing product portfolio, and strong government support for domestic manufacturing. The sector is evolving beyond a low-cost manufacturing hub to an exporter of high-quality medical devices catering to global demand.

Emergence of Indigenous players with quality products catering to global demand

Indian MedTech firms are increasingly recognized for their ability to manufacture high-quality, cost-effective medical devices that meet international standards. Once seen primarily as a market for affordable, lower-end medical devices, the Indian medical device industry is undergoing a significant transformation. A growing number of indigenous companies, such as Integris Medtech, Polymed, Micro Life Sciences, and Trivitron Healthcare, are now investing heavily in research and development, advanced manufacturing processes, and stringent quality control, enabling them to produce products that consistently stand at par with global standards across multiple equivalence criteria. Companies are expanding their portfolios to include advanced diagnostic imaging equipment, minimally invasive surgical instruments, and novel cardiac interventional devices. With a strong R&D focus and global regulatory approvals, Indian manufacturers are supplying to markets across North America, Europe, and emerging economies, challenging established multinational players. For instance, Integris Medtech, with its portfolio of over 100 products in cardiovascular, clinical diagnostics, and scientific lab solutions, serves over 60+ countries.

[19] EvaluateMedTech

Government Initiatives Accelerating Global Competitiveness

The Indian government has introduced several initiatives to strengthen the country's MedTech manufacturing ecosystem and support global expansion. The Production Linked Incentive (PLI) scheme provides financial incentives worth approximately USD 408.7 million[20] to encourage the production of high-value medical devices, reducing import dependency and enabling global-scale manufacturing. Additionally, new Medical Device Parks, with a total financial outlay of USD 47.8 million[21]. In Himachal Pradesh, Uttar Pradesh, Madhya Pradesh, and Tamil Nadu are offering plug-and-play infrastructure is being offered to accelerate domestic production for international markets.

The recently introduced National Medical Devices Policy fosters collaboration across industry and academia, creating a robust MedTech ecosystem aligned with global market needs. Meanwhile, the R&D Policy for Pharmaceuticals & Medical Devices is enhancing interdisciplinary research, supporting startups, and strengthening India's position as an innovation hub for medical technology.

Regulatory Reforms Supporting Global Market Integration

India has reformed its regulatory framework to align with global best practices, enhancing the credibility of its medical devices in international markets. The risk-based classification of medical devices, introduced in 2017, ensures compliance with stringent global standards. The perpetual licensing system for manufacturing and imports has improved the ease of doing business, allowing Indian companies to scale exports efficiently. Furthermore, the number of regulated medical devices is set to expand beyond 24 in 2024, ensuring higher quality standards and greater global acceptance of Indian-made products.

Surge in Foreign Direct Investment and Strategic M&A Activity

Foreign direct investment (FDI) in the Healthcare and MedTech sector has increased over the years, reflecting global confidence in Indian manufacturers. India has become an attractive destination for FDI in recent years, influenced by several factors that have boosted FDI. India ranked 40th in the World Competitive Index 2024, jumping 3 positions from the 43rd rank in 2021. India was also named as the 48th most innovative country among the top 50 countries, securing the 40th position out of 132 economies in the Global Innovation Index 2023. These factors have boosted FDI investments in India. Cumulative FDI inflows until June 2024 (April 2000 to June 2024) stood at USD 35.4 billion in the Healthcare industry and USD 3.3 billion in the MedTech industry.[22] With FDI inflows increasing, companies have been able to enhance production capabilities and invest in cutting-edge technology.

Private equity firms are also actively investing in Indian MedTech startups and established players, facilitating their expansion into international markets. Additionally, strategic M&A activities are enabling Indian firms to acquire global expertise, expand their geographic reach, and strengthen their product portfolios in high-demand therapeutic areas. Indian medical device firms have garnered considerable attention from PE companies due to their capabilities to offer high-quality products at low cost, competing with global MNCs. In July 2025, Abu Dhabi Investment Authority (ADIA) announced a USD 200.0 million investment for a 3% stake in Meril Life Sciences (Micro Life Sciences). In 2024, Warburg Pincus invested around USD 300.0 million in Appasamy Associates, an Indian ophthalmic equipment manufacturer, to support its expansion and innovation efforts. Similarly, in 2024, global investment firm KKR announced the acquisition of Indian medical devices maker Healthium Medtech from UK-based Apax Partners, valuing the company at approximately USD 839.0 million. Since 2017, there have been about 59 PE transactions in MedTech, with deals increasing by 3.3 times compared to pre-COVID-19 levels. Moreover, the share of medical

[20] Ministry of Chemicals and Fertilizers: Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices to promote Indigenous manufacturing of medical devices

[21] Ministry of Chemicals and Fertilizers: Medical Device Parks

[22] IBEF

devices in the total healthcare deal value has doubled from 6% between 2017 and 2020 to 11% between 2021 and mid-2024.

Table 3.4: Select recent PE investments in the Indian MedTech sector			
Investor/PE firm	**Target Company**	**Year**	**Deal Value (USD Million)**
ADIA	Meril Life Sciences (Micro Life Sciences)	2025	200
KKR	Healthium	2024	839
Warburg Pincus	Appasamy Associates	2024	300
Kotak Alt	Biorad Medisys	2024	48
Temasek	Molbio Diagnostics	2022	85
Warburg Pincus	Micro Life Sciences	2022	210

Source: Frost & Sullivan, Secondary sources

Rising insurance penetration

The burgeoning trend of rising health insurance penetration across India and other Southeast Asian countries is undeniably a pivotal factor driving the demand for advanced medical procedures, particularly those involving implants. This phenomenon is transforming healthcare accessibility, turning what were once financially prohibitive surgeries into viable options for a much larger segment of the population. As of early 2025, estimates suggest that over 50% of the Indian population has some form of health insurance coverage, be it government-funded schemes (like Ayushman Bharat Pradhan Mantri Jan Arogya Yojana - PMJAY), employer-provided group insurance, or privately purchased policies. While Southeast Asian countries have national health insurance schemes, private health insurance demand is also rising due to factors like higher risk and insurance awareness (especially post-COVID-19), and a desire for more comprehensive protection.

3.6. Different Business Models in MedTech and their Characteristics

The MedTech industry operates across multiple business models, each designed to optimize value creation based on the type of medical technology, target customer base, and regulatory environment. The choice of a business model is influenced by the level of regulation, infrastructure maturity, reimbursement mechanisms, and healthcare access.

Some of the most popular business models include:

Table 3.5: Business Models in the MedTech Industry					
Business Model	**Definition**	**Benefit to Healthcare providers**	**Benefit to MedTech Companies**	**Example**	**Best-Suited Markets**
Capital Equipment Sales	One-time sale of devices with optional service contracts	One-time upfront cost, ownership of the equipment, control over maintenance for equipment with a long lifespan	Provides immediate revenue, High sale value, and full customer ownership	CT scan, MRI, Surgical, and Lab Equipment	**Regulated Markets:** Healthcare facilities in these markets have well-established procurement processes, capital budgets, and structured

					reimbursement systems that support high upfront investments in medical technology.
Consumables-Based (Razor-and-Blade)	Lower upfront device cost, recurring revenue from consumables	Low device cost, purchase of consumables based on usage	Long-term contracts, scalable pricing model, continuous revenue, customer lock-in	Clinical Diagnostics (reagent rental)	**Regulated/Emerging Markets:** Where Hospitals and labs operate within reimbursement frameworks that ensure sustained demand for consumables, making it viable for companies to adopt a recurring revenue model.
Leasing & Subscription (Pay-per-Use)	Customers pay per use/test rather than an upfront purchase	Reduces financial burden, long-term engagement	Lowers entry costs, flexible payments	Medical Devices, Clinical Diagnostics, Lab Equipment	**Emerging Markets:** Many hospitals and diagnostic centers in these markets face budget constraints, making pay-per-use models more feasible. This approach helps increase access to advanced technology without requiring large capital investments.
Outcome-Based (Value-Based)	Payment tied to clinical	Risk-sharing, data-driven reimbursement	Encourages innovation,	Digital Health, AI-Based Diagnostics	**Regulated Markets:** These markets have mature value-

	outcomes and efficiency		aligns cost with patient care		based care initiatives and reimbursement structures that prioritize improved patient outcomes over volume-based purchasing. Strong data analytics infrastructure enables effective monitoring of clinical outcomes.
Direct-to-consumer (DTC)	Devices sold directly to consumers via retail and online	Empowers self-care, bypasses healthcare intermediaries	Expands market access, enhances patient engagement	Wearables, Home Diagnostics	**Both Regulated & Emerging Markets:** In regulated markets, consumer awareness and disposable income drive demand for self-monitoring devices. In emerging markets, limited healthcare infrastructure pushes consumers to seek home-based solutions.
PPP & Government Procurement	Long-term supply agreements with public health agencies	Price advantage due to large volume contract, improved access to quality equipment, and promoting the development of	Ensures large-scale adoption, stable revenue, high-volume sales, and public sector funding	Medical Devices, Clinical Diagnostics, Public Health	**Emerging Markets:** Governments in these markets play a crucial role in healthcare procurement due to financial

		domestic medical device companies			limitations in private healthcare. Public-private partnerships help expand access to essential medical technologies at scale.

Source: Frost & Sullivan

Further, successful Medtech companies employ various strategic diversification models to enhance their market presence, innovation, and efficiency. The choice of models impacts scalability, cost structure, and competitive positioning. Companies adopting a mix of revenue and strategic diversification models help ensure sustained revenues. For instance, diagnostic companies that provide automated diagnostic equipment might lease the machines and then sell the required test cartridges or reagents on a subscription basis. This ensures that the equipment is used, and the company has a constant flow of consumable sales. Similarly, companies selling radiology equipment (e.g., Siemens, GE, Philips) and patient monitoring devices (e.g., Masimo, Nihon Kohden) are integrating AI into their equipment and offering AI-powered services such as predictive maintenance, Image analysis, and Data analytics as part of a bundled package.

Some of the most commonly used strategic diversification models include:

Table 3.6: Prevalent strategic diversification Models in the MedTech Segment

Strategic Diversification Models	Description	Advantages
Build (In-house product development)	The company designs, manufactures, and commercializes its own medical devices.	Full control over quality, regulatory compliance, and intellectual property; long-term cost efficiency; stronger brand identity.
Buy (Acquiring companies)	Expanding through mergers or acquisitions of MedTech companies with established products or technologies.	Accelerates market entry; leverages existing expertise and distribution channels; expands product portfolio with proven innovations.
Partnership	Selling through partnership with local/domestic players by leveraging regional expertise, distribution networks, and regulatory knowledge	Enables rapid market expansion; requires lower capital investment; offers diversification and flexibility; and helps to leverage customer touchpoints. Given different regulatory compliance, OEMs prefer to partner with local players to leverage customer touchpoints and knowledge of local regulations.

Source: Frost & Sullivan

Benefits of the Consumable-driven sales model

Clinical Diagnostics

Recurring revenue from reagent sales in clinical diagnostics plays a critical role in enhancing customer stickiness (long-term loyalty) by creating predictable, sustainable revenue streams and fostering strong relationships between suppliers and healthcare providers. Below is a detailed analysis of how this model drives customer retention:

1. Dependence on proprietary reagents

Instrument-reagent compatibility: Many diagnostic instruments (e.g., PCR machines, immunoassay analyzers) require proprietary or specialized reagents that are only available from the manufacturer. This "lock-in" effect forces labs to continue purchasing reagents from the same supplier to avoid costly equipment replacements or disruptions in testing workflows.

Technical barriers to switching: Switching reagent suppliers often requires re-validation of tests, recalibration of instruments, and staff retraining, which are time-consuming and expensive. Labs are incentivized to stay with a trusted supplier to avoid these costs.

Benefits of reagent standardization: Using consistent reagents minimizes variations in experimental or production outcomes. This leads to more reliable and reproducible results. Moreover, standardized reagents allow for tighter control over chemical reactions and processes. This can optimize yields, reduce waste, and improve results.

2. Predictable revenue Streams

Stable cash flow: Reagent sales generate consistent, high-margin revenue that allows suppliers to invest in customer support, R&D, and service agreements. This financial stability enhances the supplier's ability to meet customer needs, further strengthening loyalty. Reagents account for a larger share of revenue in the Clinical Diagnostics market.

Subscription models: Some companies offer subscription-based reagent supply plans, ensuring steady usage and reducing the likelihood of customers seeking alternatives.

3. Value-Added Services

Technical support & training: Suppliers often bundle reagent sales with technical assistance, training, and maintenance services. This added value reduces operational risks for labs and builds trust. After-sales service is important in segments such as clinical diagnostics.

Customized Solutions: Suppliers may develop tailored reagent kits for specific tests (e.g., rare disease diagnostics), creating a unique dependency.

Data insights: Suppliers may provide analytics on reagent usage to help labs optimize workflows, adding strategic value.

Recurring revenue from reagent sales creates a virtuous cycle of customer loyalty by combining technical dependency, financial predictability, and value-added services. Long-term reagent supply agreements with customers ensure a high customer retention rate for Clinical Diagnostic companies.

Intravascular Lithotripsy

Similar to clinical diagnostics, Intravascular Lithotripsy (IVL), exemplified by the pioneer Shockwave Medical (now part of Johnson & Johnson MedTech), is heavily reliant on a consumable-driven sales model. IVL technology adapts principles from urologic lithotripsy (kidney stone fragmentation) to the cardiovascular system. It delivers precisely focused sonic pressure waves to crack calcium within arterial walls, making the vessel more compliant and allowing for optimal stent expansion. A typical IVL system consists of three main components: a reusable generator, a reusable

connector cable, and a single-use, disposable catheter, which is a critical consumable and is a balloon-based catheter with integrated emitters that generate the sonic waves. In this model, the initial capital equipment (the generator) is a one-time purchase, while the high-value, single-use component (the catheter) is purchased for every procedure. Shockwave IVL represents a next-generation solution for treating heavily calcified vascular lesions. It combines a balloon catheter platform with sonic pressure waves to safely and predictably fracture intimal and medial vascular calcium, optimizing vessel compliance for subsequent stent deployment.

3.7. Importance of Diversification (Products and Geographies)

Companies catering to different customer segments with a diversified portfolio of products can de-risk operations by avoiding customer/product concentration risk. Most of the leading global companies, such as Abbott, Johnson & Johnson MedTech, Medtronic, Boston Scientific, and Becton Dickinson, have diversified product offerings. These global leaders are recognized for their innovations in drug-eluting stents, catheters, and other complex cardiac devices.

Leading global MedTech companies have successfully achieved growth by not only building an internal innovation pipeline but also adopting an M&A strategy to build a diversified portfolio and grow at a faster rate. Companies catering to diverse customer segments with a broad portfolio of products can mitigate operational risks by reducing dependence on any single product or customer group. This approach helps avoid concentration risk and enhances resilience against market fluctuations. Such diversification also requires a deep understanding of regulatory complexities that pure pharma or MedTech companies need to understand before adopting such a strategy. New entrants face substantial barriers, needing to invest heavily to replace established systems and relationships, and to overcome the complexities of local market requirements.

For example, Abbott Laboratories, a global leader in medical technology, has strategically leveraged mergers and acquisitions to build a diversified portfolio and sustain long-term growth. The company operates across diagnostics, medical devices, nutrition, and pharmaceuticals, serving multiple healthcare segments. One of Abbott's most significant acquisitions was St. Jude Medical in 2017, which strengthened its position in cardiovascular and neuromodulation devices. This USD 25.0 billion acquisition expanded Abbott's capabilities in heart failure, atrial fibrillation, and chronic pain management. Additionally, the purchase of Alere in the same year enhanced Abbott's diagnostics segment, particularly in point-of-care testing, further solidifying its presence in the rapidly growing diagnostics market. Similarly, the purchase of Cardiovascular Systems in 2023 added atherectomy devices to Abbott's range of vascular-disease-focused products.

Through strategic M&A, Abbott has not only expanded its product range but also accelerated revenue growth and market penetration. For instance, Abbott's revenue increased from USD 27.4 billion in 2017 to USD 42.0 billion in 2024. Its diversified portfolio helps mitigate risks associated with regulatory changes, market downturns, and competitive pressures, ensuring a stable and scalable business model. Similarly, other companies such as Johnson and Johnson, Medtronic, Stryker, and Boston Scientific have leveraged M&A strategies to achieve growth and product diversification.

Further, MedTech companies leverage M&A strategies to tap into new and emerging markets to increase their customer base and revenue streams. Acquiring companies with established distribution networks and local expertise in specific regions is a common strategy. Acquiring companies with established regulatory relationships can streamline market entry and reduce compliance risks. Emerging markets often present significant growth opportunities due to their expanding middle classes and increasing healthcare expenditures. For instance, Korea-based dental implant company, Osstem, acquired Brazil's Implacil de Bortoli for approximately USD 89.8 million.

Table 3.7: Select global MedTech leaders, key acquisitions, and divisional revenue

Company	Target	Year	Deal Value (USD Billion)	Specialty	Revenue from divisions, 2024 (USD Million)

Abbott	Optimedica	2013	0.3	Ophthalmology	**Clinical Diagnostics: 9,341** ▪ Core Laboratory: 5,235 ▪ Molecular Diagnostics: 521 ▪ Point of Care Diagnostics: 588 ▪ Rapid Diagnostics: 2,997 **Medical Devices: 18,986** ▪ Rhythm Management: 2,390 ▪ Electrophysiology: 2,467 ▪ Heart Failure: 1,279 ▪ Vascular: 2,837 ▪ Structural Heart: 2,246 ▪ Neuromodulation: 962 ▪ Diabetes Care: 6,805 **Nutritional Products: 8,413** **Established Pharmaceutical Products: 5,194**
	Tendyne Holdings	2015	0.3	Cardiovascular	
	St. Jude Medical	2016	25.0	Cardiovascular	
	Alere	2016	5.3	Clinical Diagnostics	
	Cephea Valve Technologies	2019	Undisclosed	Cardiovascular	
	Walk Vascular	2021	Undisclosed	Vascular therapy	
	Cardiovascular Systems Inc.	2023	0.9	Cardiovascular	
Johnson & Johnson	Biosense Webster	1997	0.4	Cardiovascular	**MedTech: 31,857** ▪ Surgery: 9,845 ▪ Orthopedics: 9,158 ▪ Cardiovascular: 7,707 ▪ Vision: 5,146 **Innovative Medicine (Biopharma business) : 56,964**
	Depuy	1998	3.5	Orthopedics	
	Synthes	2012	19.7	Orthopedics	
	Coherex Medical	2015	Undisclosed	Cardiovascular	
	Auris Health	2019	3.4	Surgical Robotics	
	Abiomed	2022	16.6	Cardiovascular	
	Laminar	2023	0.4	Cardiovascular	
	Shockwave	2024	13.1	Cardiovascular	
	V-Wave	2024	0.6	Cardiovascular	
Boston Scientific	Axonics	2024	3.7	Neuromodulation	**Medical and Surgical solution: 5,993** ▪ Endoscopy: 2,687 ▪ Urology: 2,200 ▪ Neuromodulation: 1,106 **Cardiovascular: 10,755** ▪ Cardiology: 8,344 ▪ Peripheral interventions: 2,410
	Lumenis	2021	1.0	Laser therapy	
	Preventice Solutions	2021	1.2	Cardiovascular	
	Baylis Medical		1.8	Cardiovascular	
	Relievant Medsystems	2023	0.9	Neuromodulation	
	Silk Road Medical, Inc	2024	1.2	Neurovascular	
	Cortex	2024	Undisclosed	Cardiovascular	
	Bolt Medical	2025	0.9	Cardiovascular	

Source: Frost & Sullivan

Most of the acquisitions by leading global MedTech companies were in the cardiovascular segment due to its sustained growth potential and the introduction of novel, minimally invasive therapies. M&As in MedTech are

growing year over year due to the increasing appetite for growth and product diversification by leading MedTech companies. The number of MedTech M&A deals increased from 254 in 2019 to 305 in 2024. Similarly, the total M&A value increased from USD 55.3 billion in 2019 to USD 63.1 billion in 2024.[23]

Among the leading Indian companies having a presence in both cardiovascular and clinical diagnostics, Integris Medtech leads in the number of acquisitions (10). Moreover, Integris Medtech is one of the only two Indian companies manufacturing all 3 classes of medical devices (Class I, II, and III).

Table 3.8: Major Indian companies in Cardiovascular and Clinical diagnostics, and the Number of acquisitions

Company	Portfolio focus	No. of Acquisitions (as of March 2025)	Degree of Diversification	Presence in Class I, II, and III of Medical Devices
Integris Medtech	Cardiovascular and Clinical Diagnostics, Scientific Lab Solutions	15	High	Class I, II, and III
Sahajanand Medical Technologies	Cardiovascular	3	Low	Class III
Trivitron Healthcare	In-vitro diagnostics, Imaging	3	Medium	Class I and II
Molbio Diagnostics	Clinical diagnostics	3	Low	Class II
TransAsia Bio-Medicals	In-vitro diagnostics	2	Low	Class I and II
Polymed	Infusion, Vascular Access	1	Medium	Class I and II
Micro Life Sciences (Meril Life Sciences)	Cardiovascular, In-vitro diagnostics, Implants	0	High	Class I, II, and III
Relisys Medical Devices	Cardiovascular	0	Low	Class III

Source: Company websites, Press releases, Pitchbook, Frost & Sullivan

Integris Medtech has acquired companies such as Hausen-Bernstein Co. Ltd, (a notable provider of in-vitro diagnostic products in Thailand), Research Instruments Group (provider of scientific and laboratory instrumentation in Singapore, Malaysia, Thailand, and Vietnam), CPC Diagnostics (medical device manufacturer and distributor from India with presence in Sri Lanka and Bangladesh), Lifeline Diagnostics (Philippines distributor of Clinical Diagnostics and Scientific Lab Solution Products) and Chemopharm (Malaysian distributor of medical products and solutions). Integris Medtech is the second largest Indian headquartered diversified MedTech platform in terms of operating revenue for Fiscal 2025. The company operates in two of the largest segments of the overall global MedTech market, Cardiovascular and clinical diagnostic devices.

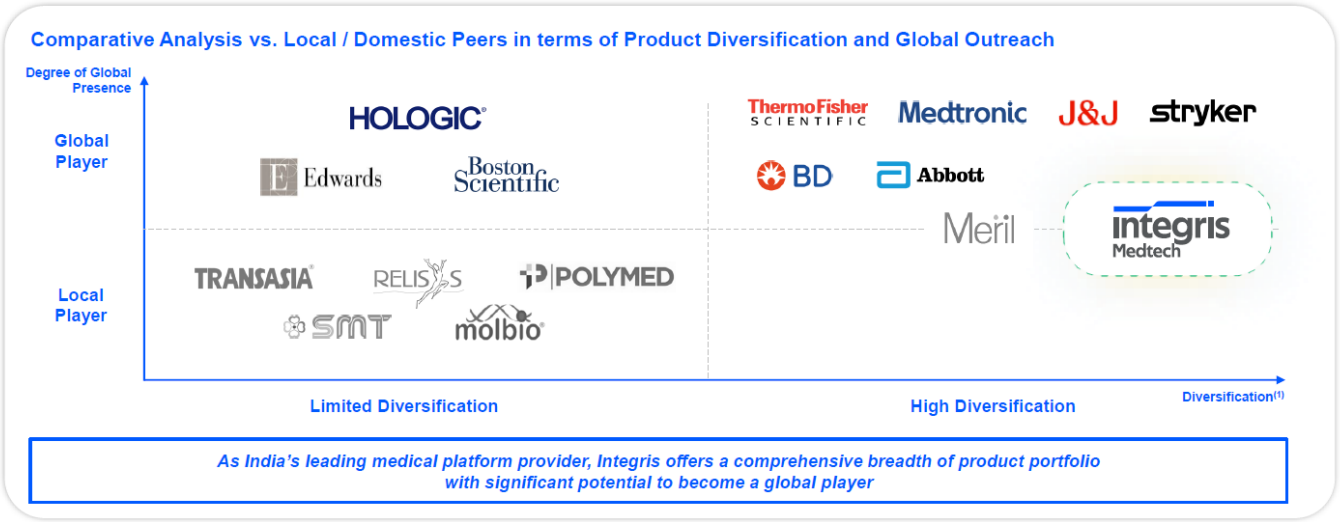
Table 3.9: Diversification intensity and example of global companies

Degree of Diversification	Select Companies
High	Mindray, Baxter, Stryker, Siemens, Johnson & Johnson, Medtronic, Abbott, ThermoFisher, **Integris Medtech**
Medium	Hologic, Steris, Terumo, Boston Scientific, GE Healthcare, Bio-Techne
Low	Align Technology, United Imaging, ResMed, Edwards Lifesciences, Intuitive Surgical, bioMérieux, Fresenius, Straumann, Dexcom, Alcon

Source: Pitchbook, Frost & Sullivan

[23] JP Morgan 2024 Medtech Industry Insights

Integris is the only Indian Diversified Medtech Player poised to Emerge as a Global Player



Source: Frost & Sullivan

4. Overview of the Global Cardiovascular Market

The cardiovascular device industry is at the forefront of innovation, continuously advancing toward safer, more effective, and less invasive solutions that not only extend life expectancy but also enhance the quality of life for millions of patients worldwide. As we move forward, the interplay between medical technology, regulatory advancements, and healthcare delivery models will shape the future trajectory of cardiovascular disease management across the globe.

Cardiovascular diseases (CVDs) represent the leading cause of mortality worldwide, accounting for nearly 20.5 million deaths annually in 2021, which translates to about one-third of total global deaths. The annual CVD mortality is expected to increase to 22.2 million by 2030 and 35.6 million by 2050.[24] The burden of CVD continues to rise due to an aging population and increased prevalence of risk factors such as hypertension, diabetes, obesity, smoking, and sedentary lifestyles. It is estimated that over a billion people globally live with some form of cardiovascular disease, ranging from coronary artery disease and heart failure to arrhythmias and valvular disorders.[25]

The impact of cardiovascular diseases is not only measured in terms of mortality but also the quality of life lost and the economic burden on healthcare systems. CVDs contributed to nearly 430 million disability-adjusted life years (DALYs) lost annually in 2021, which has increased from about 298 million in 1990, and the share of CVD of the total disease burden has increased from 11.5% in 1990 to 14.9% in 2021.[26] In 2021, there were 36.8 million prevalent cases of cardiovascular disease and 1.66 million cardiovascular disease deaths across the ASEAN region. The total number of DALYs was 42.4 million, with cardiovascular disease the leading cause of disease burden in the region. Compared with 1990, the number of individuals with cardiovascular disease has increased by 148%.[27] Similarly, East Asia and South Asia were the top 2 regions with the highest share of CVD deaths, 26.8% and 19.1%, respectively.[28]

[24] WHO: Cardiovascular Diseases
[25] World Heart Federation
[26] Global Burden of Cardiovascular Diseases and Risk Factors, 1990–2019
[27] The Lancet Public Health, Volume 10, Issue 6, e467 - e479
[28] Cureus; 2024 Nov 24;16(11):e74333.

Medical devices have fundamentally transformed the landscape of cardiovascular disease management, improving survival rates, reducing hospitalizations, and enhancing patients' quality of life. From the early development of pacemakers and mechanical heart valves to today's cutting-edge transcatheter therapies, the cardiovascular device market has seen a remarkable evolution.

- In the hospital setting, cardiovascular devices are critical in acute care, from percutaneous coronary interventions (PCI) with stents and balloons to complex surgical procedures involving artificial heart implants and ventricular assist devices (VADs). Advanced imaging modalities such as intravascular ultrasound (IVUS), Optical Coherence Tomography (OCT), and angiography have significantly improved early detection and treatment planning, leading to better outcomes and reduced complications. Among these, ACIST HDi is a high-definition IVUS imaging system that provides superior vessel visualization, while ACIST CVi is an advanced contrast delivery system that offers precise contrast dosing to minimize nephrotoxicity. Both technologies enhance procedural safety, accuracy, and efficiency in the cath lab.
- In ambulatory and outpatient settings, the availability of minimally invasive solutions such as catheter-based ablation for arrhythmias, implantable cardiac monitors, and wearable ECG devices has enabled early diagnosis, remote monitoring, and timely interventions, reducing the need for prolonged hospital stays and emergency admissions.
- In home-care settings, technological advancements have paved the way for remote patient monitoring (RPM) solutions that allow continuous tracking of vital parameters, including heart rate, blood pressure, and arrhythmias. Wearable medical technology, such as smartwatches with ECG functionality, is playing an increasing role in the early detection of atrial fibrillation (AFib) and other cardiovascular anomalies, enabling timely medical interventions.

The increasing integration of digital health tools, artificial intelligence, and machine learning, and novel technologies like polymer-free stents in cardiovascular care is further optimizing diagnosis, treatment personalization, and disease management. AI-powered ECG interpretation, automated risk stratification models, and telehealth consultations are improving patient engagement and accessibility to specialized care, particularly in underserved regions. The increasing advancements in next-generation biomaterials, minimally invasive interventions, and hemodynamic monitoring technologies are further optimizing cardiovascular diagnosis, treatment personalization, and disease management. Bioabsorbable stents, polymer-coated drug-eluting balloons, and transcatheter valve replacement systems are enhancing procedural outcomes and reducing long-term complications. Innovations such as real-time blood flow sensors, next-gen pacemakers with energy-harvesting capabilities, and catheter-based hemodynamic monitoring are improving early disease detection and post-surgical recovery, particularly for high-risk patients.

Furthermore, regulatory frameworks and reimbursement policies are evolving to support the adoption of advanced cardiovascular devices. Governments and healthcare agencies are investing in early screening programs, value-based healthcare models, and reimbursement structures that encourage the use of innovative devices to prevent disease progression and reduce long-term healthcare costs.

Cardiovascular devices encompass a wide range of products designed for the diagnosis, treatment, and management of cardiovascular diseases. These devices can be broadly classified into three main categories:

- **Diagnostic Devices:** Used for early detection and continuous monitoring of cardiovascular conditions, these devices include electrocardiograms (ECG), echocardiograms, Holter monitors, cardiac MRI, CT angiography, and blood pressure monitors. Examples of companies in this category include Omron, Philips, GE Healthcare, etc.
- **Therapeutic Devices:** These devices aid in the treatment and management of CVDs. Examples include stents, implantable pacemakers, defibrillators, ventricular assist devices (VADs), and remote patient

monitoring solutions. Examples of companies in this category include Medtronic, Abbott, Edwards Lifesciences, Boston Scientific, etc.

- **Surgical Devices:** Devices used in interventional and surgical procedures, including catheters and other surgical solutions. Examples of companies in this category include Terumo, B Braun, Teleflex, etc.

Some of the most commonly used cardiovascular devices include:

Table 4.1: Examples of Commonly Used Cardiovascular Devices

Product Category	Uses	Types	Regulatory Risk Classification (FDA/CDSCO)	Sample image
Stents	Small mesh tubes are inserted into narrowed arteries to keep them open and maintain blood flow. Used in percutaneous coronary interventions (PCI) for treating coronary artery disease (CAD).	- **Bare-Metal Stents (BMS)**: Simple metal stents without drug coatings, used to provide structural support to arteries. - **Drug-Eluting Stents (DES)**: Coated with medication to prevent restenosis (re-narrowing of the artery after stent placement), offering improved long-term vessel patency and safety. - **Bioabsorbable Stents**: Designed to dissolve over time, reducing long-term complications.	**Class III/ D (Highest-risk)**: Requires rigorous clinical testing and approval due to their implantation and direct impact on patient health.	
Balloons	Inflatable devices are used to open narrow or blocked arteries during angioplasty procedures, facilitating stent placement or restoring blood flow.	- **Plain Old Balloon Angioplasty (POBA)**: Standard balloon inflation to open the artery. - **Drug-Coated Balloons (DCB)**: Coated with drugs to prevent restenosis post-procedure.	**Class II or III**: Depending on drug-coating and intended use.	

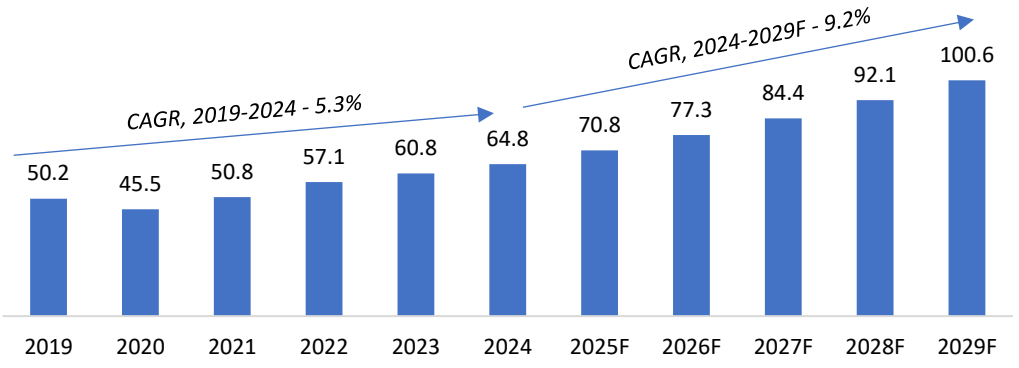
Catheters	Flexible tubes are inserted into the body for diagnostic and therapeutic procedures, including angioplasty, electrophysiology studies, and ablation therapy.	- **Guiding Catheters**: Used to deliver devices such as stents or balloons to the treatment site. - **Diagnostic Catheters**: Used for imaging and measuring blood flow dynamics. - **Ablation Catheters**: Used to destroy abnormal heart tissue causing arrhythmias.	**Class II or III**: Depending on invasiveness and therapeutic function.	

Source: Frost & Sullivan

4.1. Global Cardiovascular Devices Market

The global cardiovascular device market has witnessed consistent growth over the past decade, driven by increasing cardiovascular disease (CVD) prevalence, technological advancements, and rising healthcare expenditure. In 2024, the market is estimated to be valued at approximately USD 64.8 billion, reflecting a 5.3% CAGR over the past five years. The growth trajectory is expected to continue, with projections indicating the market will reach USD 100.6 billion by 2029, growing at a 9.2% CAGR between 2024 and 2029. This expansion is fueled by rising demand for minimally invasive procedures, improved patient access to advanced treatments, and the increasing adoption of home-based cardiovascular monitoring solutions.

Exhibit 4.1: Global Cardiovascular Device Market (USD Billion), 2019-2029F



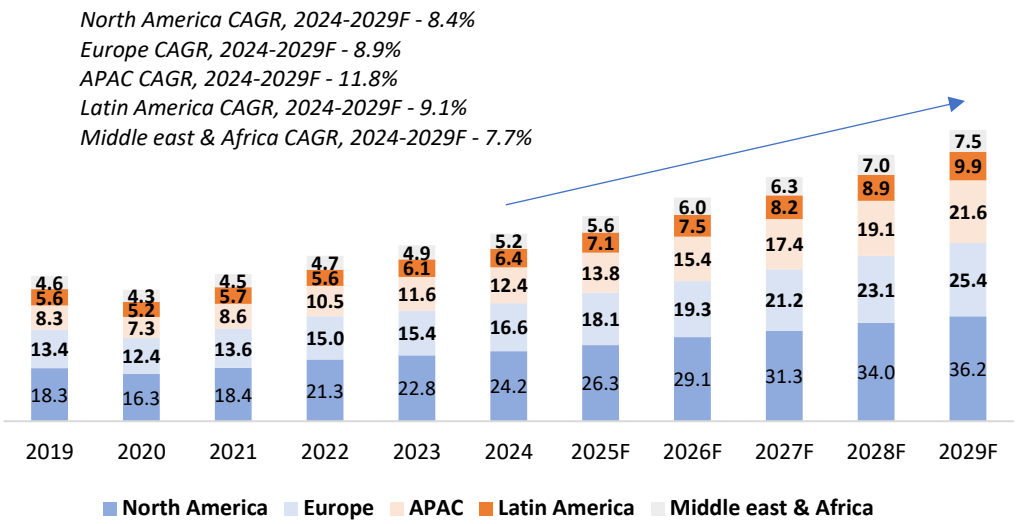
Source: Frost & Sullivan

4.1.1. Global Cardiovascular Devices Market by Regions

The global cardiovascular device market is witnessing regional diversification, with North America and Europe leading in market share, while APAC, particularly India and China, is driving the fastest growth. Going forward,

emerging markets will play a crucial role in driving the next phase of cardiovascular device innovation and adoption, reshaping the global market landscape.

Exhibit 4.2: Cardiovascular Device Market by geographies (USD Billion), 2019-2029F

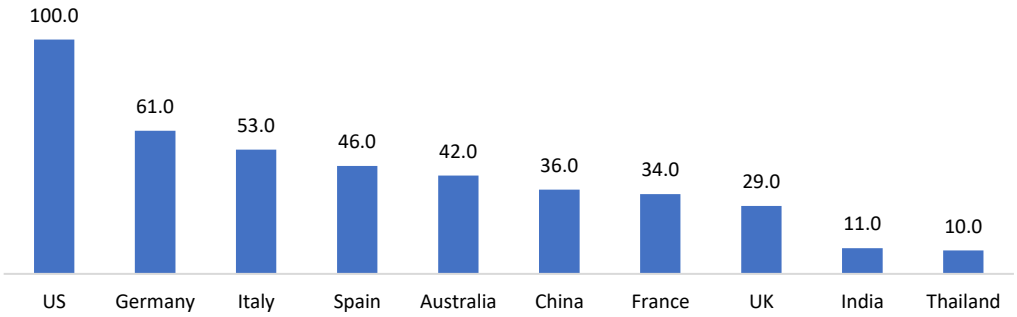


Source: Frost & Sullivan

The cardiovascular device market exhibits regional variations in terms of market size, growth rate, and product adoption, influenced by factors such as disease burden, healthcare infrastructure, regulatory environment, and reimbursement policies. While North America and Europe remain the largest markets due to advanced healthcare systems and widespread adoption of minimally invasive procedures, Asia-Pacific (APAC), particularly India and China, is experiencing the fastest growth, driven by increasing healthcare access and rising cardiovascular disease (CVD) prevalence.

- The North America region is valued at USD 24.2 billion in 2024. The forecasted growth in the region (CAGR of 8.4%) is lower than APAC and LATAM regions due to factors such as reimbursement pressures and regulatory challenges.
- The Europe region is valued at USD 16.6 billion in 2024, with a CAGR of 8.9% projected through 2029. While the region benefits from universal healthcare systems, strong regulatory frameworks, and the presence of leading cardiovascular device manufacturers, the growth is expected to be lower compared to APAC and LATAM. The region is witnessing rising healthcare costs and a funding crunch, which is favorable to cost-leveraged overseas players. The EU MDR, which was introduced in May 2021, has added complexities in market entry, delaying new product launches but ensuring higher safety standards. Replacing the Medical Device Directive (MDD), the EU MDR aims to enhance patient safety and improve the approval process for medical devices. For instance, the EU MDR introduces more rigorous requirements for demonstrating medical device safety and performance, including increased clinical evidence requirements, and it mandates the implementation of an UDI (Unique Device Identification) system to enhance traceability of medical devices.

Exhibit 4.3: Cost Comparison Index (reference to the US pricing) for Angioplastry Procedures

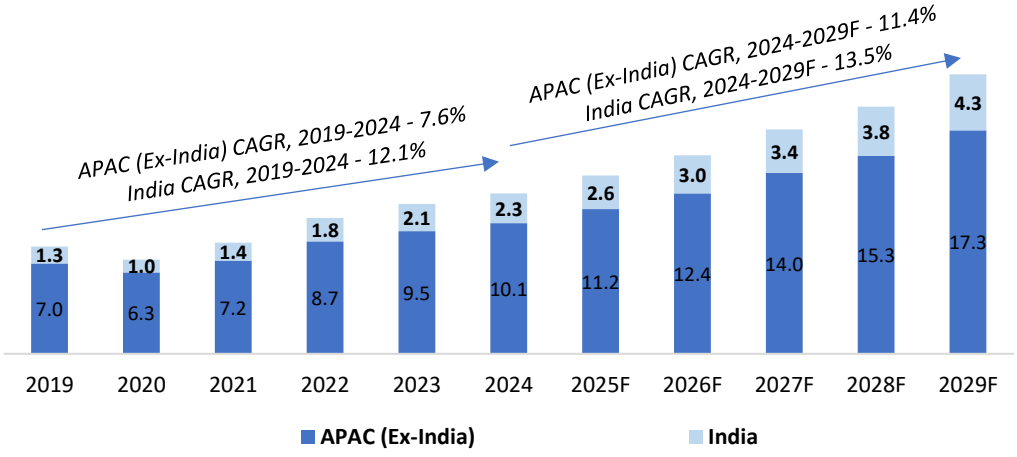


Source: Frost & Sullivan

The APAC cardiovascular device market is experiencing the fastest growth globally, projected to have a compound annual growth rate (CAGR) of 11.8% from 2024 to 2029, with a total market value reaching USD 21.6 billion in 2029. India, China, Japan, and South Korea are currently leading this market. Meanwhile, Southeast Asia, comprising countries like Indonesia, Vietnam, Thailand, Malaysia, and the Philippines, is undergoing rapid expansion due to improvements in healthcare infrastructure. The robust regional growth is accelerating the adoption of advanced interventional cardiovascular products and shaping the future trajectory of the sector.

Governments in China and India are focusing on boosting domestic production to reduce reliance on imports. China's "Made in China 2025" initiative and India's National Medical Devices Policy 2023, along with the "Make in India" initiative, aim to strengthen local industries. Additionally, emerging markets such as India, Vietnam, and Indonesia are attracting investments due to their growing middle-class populations and government efforts to expand healthcare access.

Exhibit 4.4: APAC (Ex-India) and India Cardiovascular Market (USD Billion), 2019-2029F



Source: Frost & Sullivan

Table 4.2: APAC and India Cardiovascular Device Market (% of Global, 2019 – 2029F)			
Region	**2019**	**2024**	**2029F**

	Share of Global revenue	Share of APAC revenue	Share of Global revenue	Share of APAC revenue	Share of Global revenue	Share of APAC revenue
APAC	16.5%	-	19.1%		21.5%	-
India	**2.6%**	**15.7%**	**3.5%**	**18.5%**	**4.3%**	**20.0%**

Source: Frost & Sullivan

India's National Medical Devices Policy 2023 aims for a 15% annual growth rate through 2030[29], emphasizing cost-effective innovation and local manufacturing. Southeast Asia presents untapped potential, with countries like Indonesia and Vietnam experiencing annual healthcare spending growth of 6-10%, driven by increasing disposable incomes and government healthcare reforms. Multinational companies are adapting to this landscape through local partnerships and investments in research and development to navigate regulatory complexities and seize market opportunities.

Moreover, Cath lab infrastructure is rapidly growing in emerging markets in the APAC region, such as India, China, and Indonesia, which drives the demand for minimally invasive interventional cardiovascular procedures. While India had about 650 Cath labs in 2015, it has grown to more than 2,500 in 2023, and about 200 to 250 new Cath labs are being set up each year. However, to meet the demand for cardiac and other minimally invasive procedures, India needs more than 7,500 Cath labs. Between 2017 and 2022, the number of Cath labs in Indonesia increased significantly from 181 to 310, marking a 71.3% growth. This represents the addition of 129 new facilities within just six years. Similarly, China's number of catheterization laboratories (cath labs) has increased significantly, doubling since 2010 to reach over 2,000, as of 2023.

Key market dynamics in the APAC region:

- **Rising CVD prevalence:** Cardiovascular disease (CVD) was a major cause of death and disability in the Asia-Pacific (APAC) region. In 2021, the highest number of CVD deaths in the region occurred in China (5.1 million), closely followed by India (2.9 million) and Indonesia (0.8 million)[30].
- **Aging population:** The ageing population in the region is significantly contributing to an increasing burden of cardiovascular disease (CVD). As the population ages, the prevalence of CVD and related risk factors like high blood pressure and diabetes also rises, leading to a greater number of deaths and disabilities attributable to CVD.
- **Government-led healthcare expansion:** Countries such as South Korea, India, and Thailand are investing heavily in domestic MedTech innovation to reduce dependence on Western manufacturers.
- **Increasing affordability of advanced devices**: As more local manufacturers enter the market, pricing pressures on imported devices have led to greater affordability and wider adoption.
- **Growing medical tourism:** Countries such as India, Thailand, and Malaysia are becoming regional hubs for cardiovascular procedures, attracting international patients.

India’s cardiovascular device market is experiencing one of the fastest growth rates globally, with a projected CAGR of 13.5% through 2029, reaching a market size of USD 4.3 billion by 2029 from USD 2.3 billion in 2024. The growing disease burden, increasing healthcare investments, and expanding private healthcare infrastructure are the primary drivers of growth.

Key trends shaping the Indian market:

[29] IBEF: Medical Devices Industry in India
[30] American College of Cardiology: Cardiovascular Disease Burden, Deaths Are Rising Around the World

- **High CVD prevalence:** India accounts for one-fifth of global CVD-related deaths, with over 2.6 million cases reported annually[31].
- **Rising penetration of private healthcare**: While government hospitals remain dominant, corporate hospital chains such as Apollo, Fortis, and Narayana Health are increasing accessibility to advanced cardiovascular interventions.
- **Government reimbursement for procedures:** Government-sponsored health schemes in India, both at the national and state levels, have become a significant driver of growth in the medical device sector, particularly for procedures like Percutaneous Coronary Intervention (PCI). PM-JAY has a comprehensive list of procedures and packages it covers, and cardiology is a key area. PCI is one of the most frequently utilized packages under the scheme. This includes the cost of stents and other associated treatment expenses. A major benefit of PM-JAY is that it provides cashless access to healthcare services at empaneled public and private hospitals. This eliminates the financial burden on patients at the point of service. Several Indian states have their own health schemes that operate in conjunction with or independently of PM-JAY.
- **Price control on stents and other cardiovascular devices:** The National Pharmaceutical Pricing Authority (NPPA) has capped prices on stents, significantly affecting market pricing but improving affordability.
- **Growth of domestic manufacturing:** Indigenous companies such as Integris Medtech, Sahajanand Medical Technologies (SMT), and Micro Life Sciences are expanding their footprints, challenging global players in the mid-tier and value segments.
- **Surging adoption of minimally invasive procedures:** The demand for drug-coated balloons, bioresorbable stents, and electrophysiology (EP) catheters is growing due to the increasing acceptance of catheter-based interventions over open-heart surgery.

The RoW market, which includes Latin America, the Middle East, and Africa, is relatively smaller but expanding at a CAGR of 7-10%, with a total market value of USD 17.4 billion in 2029. Growth is primarily driven by improving healthcare access, increasing medical tourism, and investments in private healthcare infrastructure.

4.1.2. Global Cardiovascular Devices Market by Product Groups

The global cardiovascular device market is segmented into several key product groups, each addressing distinct medical needs within cardiology.

- **Interventional cardiology devices,** constituting 22.0% of the market in 2024, encompass stents, catheters, and angioplasty balloons used in minimally invasive procedures to treat coronary artery disease. This segment, valued at USD 14.3 billion in 2024, is projected to reach USD 22.7 billion by 2029, growing at a CAGR of 9.8%, driven by the rising prevalence of cardiovascular diseases (CVDs), increasing adoption of percutaneous coronary interventions (PCI), and technological advancements in drug-eluting stents. While DES has long been the gold standard, Drug Coated Balloon (DCB) has emerged as a valuable alternative with distinct advantages and preferred applications. Unlike a stent, DEB does not leave a permanent implant behind. The balloon is inflated at the site of the lesion for a short period (typically 30-60 seconds), during which the drug is transferred directly to the vessel wall. The balloon is then deflated and removed. DEB eliminates risks associated with stents, such as late and very late stent thrombosis, and facilitates reintervention.
- **Structural heart devices**, representing 14.0% of the market, include transcatheter heart valves and occluders for treating valvular and congenital heart diseases. With a market size of USD 9.1 billion in 2024,

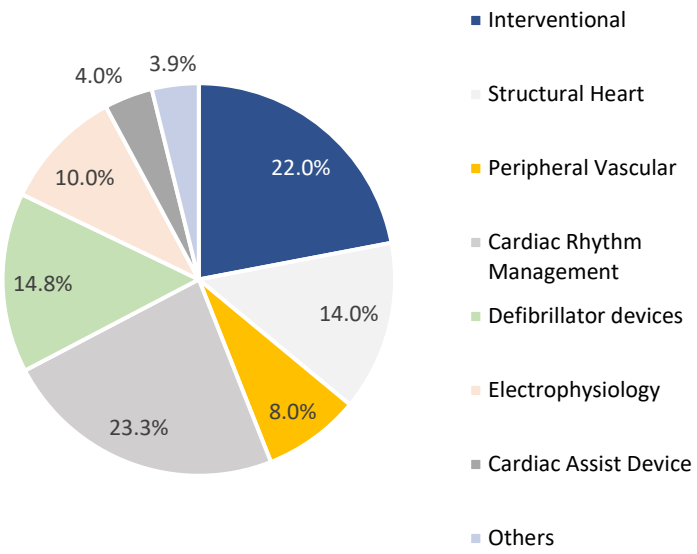
[31] Cardiovascular disease in India: A 360-degree overview

this segment is anticipated to expand to USD 14.2 billion by 2029 at a CAGR of 9.4%, propelled by an aging population, growing adoption of transcatheter aortic valve replacement (TAVR), and an increasing burden of structural heart diseases.

- **Peripheral vascular devices**, comprising 8.0% of the market, cover stents, balloons, and atherectomy devices for peripheral artery disease. Currently valued at USD 5.2 billion, it is expected to grow to USD 7.9 billion by 2029 at a CAGR of 8.8%, driven by a rising prevalence of diabetes and obesity, alongside advancements in minimally invasive treatments.
- **Cardiac rhythm management devices**, the largest segment at 23.3% of the market, include pacemakers, implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy (CRT) devices. This segment, valued at USD 15.1 billion in 2024, is forecasted to grow to USD 22.4 billion by 2029 at an 8.2% CAGR, supported by increasing incidences of arrhythmias and heart failure, along with improved reimbursement policies.
- **Defibrillator devices**, accounting for 14.8% of the market, include automated external defibrillators (AEDs) and implantable defibrillators used to prevent sudden cardiac death. The segment, valued at USD 9.6 billion, is projected to grow at a 9.1% CAGR to reach USD 14.8 billion by 2029, driven by growing awareness of sudden cardiac arrest and expansion of public-access defibrillation programs.
- **Electrophysiology devices**, constituting 10.0% of the market, include ablation catheters and mapping systems for diagnosing and treating arrhythmias. The segment, valued at USD 6.5 billion, is expected to grow to USD 9.9 billion by 2029 at an 8.9% CAGR, fueled by increasing demand for catheter-based ablation procedures and advancements in 3D mapping technologies.
- **Cardiac assist devices**, comprising 4.0% of the market, include ventricular assist devices (VADs) and intra-aortic balloon pumps (IABPs) for end-stage heart failure management. The segment, valued at USD 2.6 billion in 2024, is projected to expand to USD 4.2 billion by 2029 at the highest growth rate of 10.1%. This rapid growth is primarily driven by the increasing prevalence of end-stage heart failure, where traditional pharmacological treatments become insufficient, necessitating mechanical circulatory support. Advances in ventricular assist devices (VADs), including miniaturization, extended battery life, and improved biocompatibility, have significantly enhanced their clinical viability. Furthermore, expanding indications for long-term use, particularly as a bridge-to-transplant or even a destination therapy, have increased adoption. Additionally, the rising number of heart failure cases due to aging populations and higher survival rates from acute cardiac events has intensified demand.

- The remaining 3.9% of the market includes miscellaneous cardiovascular devices, collectively valued at USD 2.5 billion in 2024 and expected to reach USD 4.5 billion by 2029, growing at a 12.5% CAGR. This growth is attributed to the increasing adoption of novel technologies and emerging treatment modalities.

Exhibit 4.5: Global Cardiovascular Device market, share by product group, 2024



Source: Frost & Sullivan

Table 4.3: Cardiovascular Devices, Market Size and Growth by Product Group, 2024 and 2029F

Product Group	Market Size (USD Billion)		CAGR (2024-2029F)
	2024	2029F	
Interventional Cardiology	14.3	22.7	9.8%
Structural Heart	9.1	14.2	9.4%
Peripheral Vascular	5.2	7.9	8.8%
Cardiac Rhythm Management	15.1	22.4	8.2%
Defibrillator devices	9.6	14.8	9.1%
Electrophysiology	6.5	9.9	8.9%
Cardiac Assist Device	2.6	4.2	10.1%
Others	2.5	4.5	12.5%

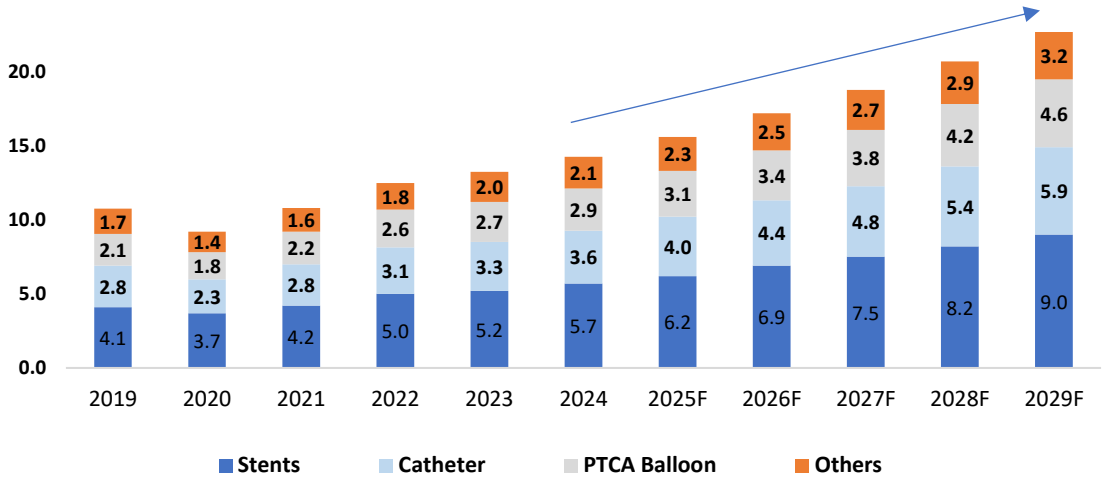
Source: Frost & Sullivan

4.1.3. Interventional Cardiology Market

The interventional cardiology segment, comprising 22.0% of the global cardiovascular device market, is poised for substantial growth, with a CAGR of 9.8% from 2024 to 2029, driven by the rising global burden of coronary artery disease (CAD) and the increasing adoption of minimally invasive procedures. Advances in drug-eluting stents (DES), bioresorbable scaffolds, and robotic-assisted interventions are enhancing procedural success rates and expanding treatment options for complex lesions. The growing geriatric population, coupled with higher risk factors such as diabetes, hypertension, and obesity, is fueling demand for percutaneous coronary interventions (PCI) over traditional open-heart surgeries. Additionally, expanding catheterization lab infrastructure in emerging markets, along with favorable reimbursement policies and increasing physician training programs, is boosting procedural volumes. The integration of artificial intelligence (AI) and intravascular imaging technologies is further optimizing patient outcomes, reinforcing sustained growth in this segment.

Exhibit 4.6: Interventional Cardiology, segment-wise revenue (USD Billion), 2019-2029F

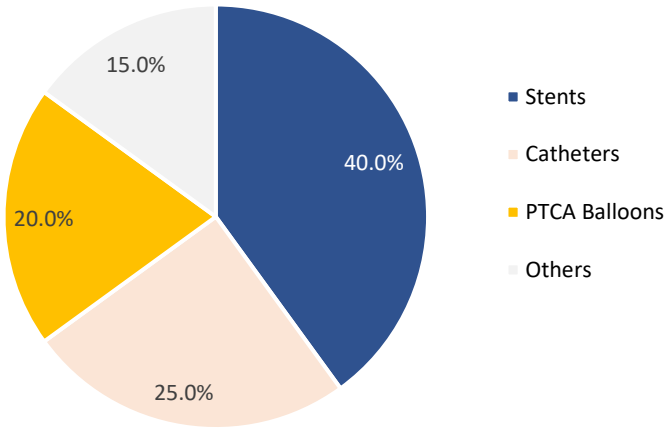
Stent CAGR, 2024-2029F - 9.6%
Catheter CAGR, 2024-2029F - 10.6%
PTCA Balloon CAGR, 2024-2029F - 9.9%



Source: Frost & Sullivan

Stents, PTCA balloons, and Catheters are the largest segments of Interventional Cardiovascular devices and collectively hold more than 80.0% share of the Interventional Cardiac Devices market in 2024.

Exhibit 4.7: Share of products in Interventional Cardiology, 2024



Source: Frost & Sullivan

Among the key product categories, stents, balloons, and catheters account for a substantial share of the cardiovascular device market. Stents dominate the sector, constituting approximately 40.0% share, followed by Catheters at 25.0% share, and PTCA Balloons at 20.0% share. The increasing use of drug-eluting stents (DES) has driven the expansion of the stent segment, whereas diagnostic and interventional catheters continue to see robust demand due to the rising number of diagnostic procedures and catheter-based interventions.

Stents: The global stent market is valued at approximately USD 5.7 billion in 2024, with drug-eluting stents (DES) accounting for 80% of this market, bare-metal stents (BMS) for a small but declining share, and bioresorbable stents for the remaining fraction. Emerging markets are also seeing increased stent adoption due to improved healthcare infrastructure and accessibility. By 2029, the stent market is projected to reach USD 9.0 billion. The stent market has expanded due to the increasing adoption of DES, which offers superior efficacy and lower restenosis rates. The bioresorbable stent segment, while still niche, is growing rapidly due to ongoing research, regulatory approvals, and long-term benefits such as reduced late-stage thrombosis risk. Meanwhile, bare-metal stents are losing market share due to their higher restenosis risk, with their use largely confined to specific patient groups where DES is not recommended. The shift toward bioresorbable stents and next-generation DES has accelerated market expansion, as these offer better long-term outcomes with fewer complications. In the medical device industry, and particularly in interventional cardiology, the assessment of long-term clinical outcomes is a key benchmark for product reliability and patient safety. Randomized controlled trials provide initial information on safety and efficacy. However, extended follow-up periods are considered important for determining a DES's ability to support durable outcomes and minimize late adverse events. Clinical benefits of DES include effective prevention of restenosis by locally delivering anti-proliferative agents (e.g., sirolimus, everolimus, ridaforolimus), long-term reduction in repeat revascularization versus bare-metal stents, and enhanced safety through thinner struts and biocompatible or biodegradable polymers. Most DES platforms currently available report clinical outcomes from three to five years of follow-up, which are generally published in peer-reviewed medical journals. A comparatively smaller number of DES technologies globally have published data tracking patient outcomes over 10 years. The development of polymer-

free stents (PFS) is a key focus for several medical device companies aiming to address the limitations of traditional polymer-coated drug-eluting stents (DES), such as reducing inflammation and improving biocompatibility. Companies such as Biosensors International, B. Braun Melsungen AG, and Integris Medtech have developed polymer-free stents.

Catheters: The catheter market, valued at USD 3.6 billion in 2024, is projected to grow at the highest CAGR of 10.6% over the next five years. The segment is split into diagnostic catheters, interventional catheters, and electrophysiology (EP) catheters. The electrophysiology catheter market is expanding rapidly, driven by the increasing number of ablation procedures for atrial fibrillation and the rising adoption of 3D mapping technology. Interventional catheters remain essential for procedures such as angioplasty and stenting, while diagnostic catheters maintain steady demand, bolstered by improvements in imaging and real-time hemodynamic monitoring. The surge in electrophysiology procedures is driving demand for EP catheters, while AI-powered robotic-assisted interventions are improving precision and efficiency in interventional catheter usage. By 2029, the catheter market is projected to reach USD 5.9 billion.

PTCA Balloons: The PTCA balloon market will be valued at USD 2.9 billion in 2024, comprising 20.3% of the total interventional cardiology market. In interventional cardiology, PTCA balloons are essential for dilating narrow coronary arteries. The commonly termed "workhorse PTCA balloon" serves as the versatile, go-to catheter used in the majority of routine angioplasty procedures. Semi-compliant balloons are typically preferred as workhorse devices for lesion preparation, while non-compliant balloons are used more selectively for post-dilation and high-pressure dilatation. Notably, non-compliant balloons with innovative twin-layer designs provide precise and consistent expansion, delivering dependable performance in complex cases where conventional balloons may be inadequate. The PTCA balloon segment is dominated by normal angioplasty balloons, which account for the majority share (60.0%), followed by cutting/scoring balloons (32.0%) and drug-coated balloons (DCB) (8.0%). DCB delivers antiproliferative medication (typically paclitaxel) during angioplasty, making them suitable for in-stent restenosis, small-vessel disease, and layers where stenting is undesirable. They leave no permanent implant and are associated with rapid drug transfer, reduced inflammation, and positive vessel remodeling. The adoption of DCB is increasing, owing to its ability to reduce restenosis without requiring a permanent implant, making it particularly useful in patients with small vessel disease or high bleeding risk. Cutting balloons are also gaining traction, particularly in cases of resistant stenosis and in-stent restenosis treatment. The shift away from permanent implants in some patient populations is fueling drug-coated balloon adoption, with the market expected to reach USD 4.6 billion by 2029, growing at a CAGR of 9.9%.

Table 4.4: Interventional Cardiovascular Devices, Market Size and Growth by segments, 2024 and 2029F

Product Group	Market Size (USD Billion)		Growth (2024-2029F)
	2024	2029F	
Stents	5.7	9.0	9.6%
PTCA Balloons	2.9	4.6	9.9%
Catheters	3.6	5.9	10.6%

Source: Frost & Sullivan

4.2. Competitive Landscape of the Global Cardiology Market

The cardiovascular device industry remains highly dynamic and fragmented, with companies competing across innovation, affordability, and regulatory approvals.

The global cardiovascular device market is highly competitive, dominated by multinational MedTech companies with extensive product portfolios, strong R&D capabilities, and widespread geographic presence. These companies are continuously investing in technological advancements, strategic partnerships, and regulatory approvals to maintain market leadership. In contrast, Indian companies are expanding rapidly, focusing on cost-effective innovations, local manufacturing, and increasing exports to emerging markets.

Global MedTech giants such as Medtronic, Abbott, Terumo Corporation, B. Braun, Biotronik, MicroPort Scientific Corporation (MicroPort), and Boston Scientific lead the market, benefiting from their strong distribution networks, innovative product pipelines, and well-established regulatory approvals. These companies leverage broad product portfolios, extensive research and development capabilities, and strong regulatory credentials, and some of them are pioneers in drug-eluting stents (DES), bioresorbable scaffolds, electrophysiology catheters, and structural heart devices, catering to hospitals and specialty cardiac centers worldwide.

The Indian cardiovascular device market has emerged as a key growth hub, with domestic manufacturers such as Integris Medtech, Micro Life Sciences, and Sahajanand Medical Technologies (SMT). Indian companies are focused on affordable alternatives to imported devices, government pricing regulations, and expansion into international markets. Many of these firms are increasingly investing in R&D and obtaining international certifications (e.g., CE marking and US FDA approval) to enhance their global competitiveness. For instance, Integris Medtech's DES products, such as ISAR SUMMIT and VIVO ISAR™ (the World's first polymer-free Dual DES), and SMT's Supraflex Cruz DES stent, are CE approved. In the medical device industry, and particularly in interventional cardiology, the assessment of long-term clinical outcomes is a key benchmark for product reliability and patient safety. Randomized controlled trials provide initial information on safety and efficacy. However, extended follow-up periods are considered important for determining a DES's ability to support durable outcomes and minimize late adverse events. Most DES platforms currently available report clinical outcomes from three to five years of follow-up, which are generally published in peer-reviewed medical journals. A comparatively smaller number of DES technologies globally have published data tracking patient outcomes over 10 years. Integris Medtech's Vivo ISAR" Polymer-Free Sirolimus Eluting Stent, the world's longest studied drug-eluting stent, with 10 years of clinical data on safety and efficacy[32] and it is the world's first dual-drug, polymer-free sirolimus-eluting stent, combining a microporous cobalt-chromium scaffold with a proprietary excipient matrix of sirolimus, probucol, and shellac resin. Indian companies are focusing on cost-effective innovations and CE certification approvals to penetrate international markets, while global players prioritize US FDA approvals and breakthrough designations to maintain leadership. Regional players address demand for cost-effective, high-quality diagnostics across emerging markets, while increasingly investing in research and development and regulatory approvals to expand their footprints internationally. Companies in emerging markets such as India and China have established a strong presence in Southeast Asian, the Middle East and Africa, and European markets, benefiting from high-quality, cost-competitive products, and successfully competing against global MNCs.

Table 4.5: Competitive Landscape of the select companies in the Cardiovascular Market

Select companies	Headquarters	Operational Footprint	Major Interventional Cardiology Product Portfolio*
Medtronic	Dublin, Ireland	North America, Europe, APAC, Latin America, Middle East & Africa	Drug-eluting stents (DES), bare-metal stents (BMS), balloon catheters
Abbott	Illinois, USA	Global presence across all major markets	DES, bioresorbable stents, and coronary balloons

[32] Journal of American Clinical Cardiology; Vol. 76 No. 2

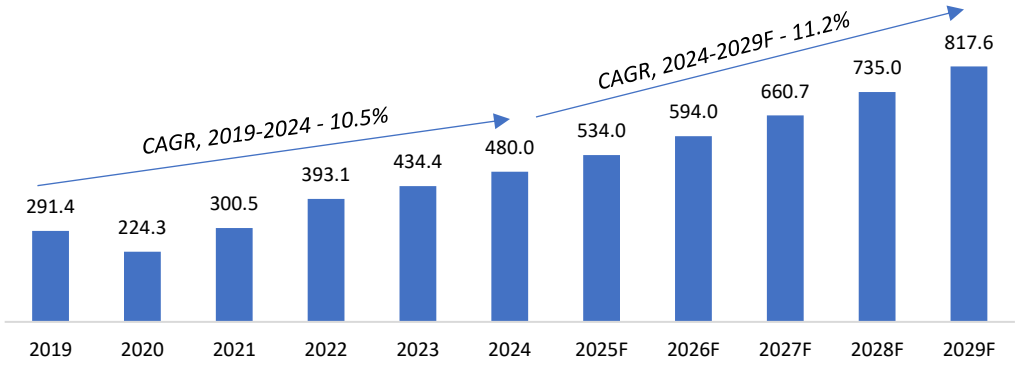
Boston Scientific	Massachusetts, USA	North America, Europe, APAC, Latin America, Middle East & Africa	DES, peripheral stents, DCB, embolic protection devices
Terumo Corporation	Tokyo, Japan	Strong presence in Japan, APAC, Europe, and North America	BMS, DES, radial access catheters, guidewires, DCB
B. Braun	Melsungen, Germany	Europe, North America, APAC, Latin America	Coronary stents, DCB, vascular closure devices
Biotronik	Berlin, Germany	Europe, North America, APAC, Middle East	DES, peripheral stents
MicroPort	Shanghai, China	North America, Europe, APAC, Latin America, Middle East & Africa	DES, PTCA Balloon, PCI accessories
Integris Medtech	Delhi NCR, India	India, Europe, Latin America, APAC	DES, BMS, DCB, coronary balloons, Coronary Intra-vascular Lithotripsy, vascular accessories (guiding/diagnostic catheter, guide wire, balloon inflation device, introducer sheath, PBMV balloons, PTFE coated angio tube, aspiration catheter kit, Y-connecter kit, introducer needle, etc.)
Micro Life Sciences	Gujarat, India	India, Asia-Pacific, Latin America, Europe, Africa	DES, bioresorbable stents, and electrophysiology catheters
Sahajanand Medical Technologies (SMT)	Gujarat, India	India, APAC, Middle East, Europe, Latin America	DES, bioresorbable stents, balloon catheters, peripheral vascular devices, drug-coated PTA balloons, vascular accessories
Relisys Medical Devices	Hyderabad, India	India, APAC, Africa	DES, BMS, peripheral vascular devices

*Source: Company website, Frost & Sullivan. *Excludes devices of structural heart, electrophysiology, pacemaker, ICD, embolic protection, and others. Note: Operational footprint is not limited to Interventional Cardiology products and devices.*

4.3. Indian Interventional Cardiology Market

The Interventional Cardiology market in India is valued at USD 480.0 million in 2024. The market has historically grown from USD 291.4 million at a CAGR of 10.5%, and it is expected to grow at a higher rate of 11.2% in the forecast period to reach USD 817.6 million in 2029.

Exhibit 4.8: Indian Interventional Cardiology Market (USD Million), 2019-2029F



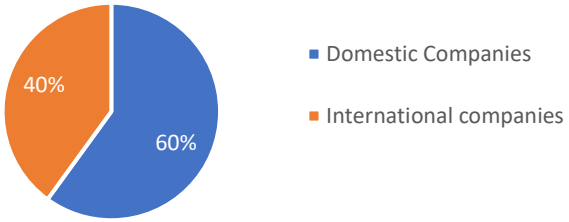
Source: Frost & Sullivan

Cardiovascular diseases (CVDs) account for nearly one-third of all deaths in the country, with a prevalence rate of around 7.5%. The burden of CVDs in India is expected to increase in the coming years due to the aging population, changing lifestyles, and rising rates of obesity, diabetes, and hypertension. CVDs affect Indians more frequently and at a younger age than individuals in developed countries.[33] Moreover, the market is propelled by an increase in the diagnosis of CVDs and the increasing adoption of minimally invasive surgeries. As per research conducted in Pradhan Mantri Jan Arogya Yojana (PM-JAY) beneficiaries, there has been an annual increase of 3.7%, 13.1%, 12.6%, and 12.9% in the number of coronary intervention procedures for the years 2017, 2018, 2019, and 2021, respectively. Similarly, the usage of drug-eluting stents (DES) has also shown an annual increase of 8.9%, 14.7%, 10.5%, and 13.3%, respectively, for the same years.[34]

In the domestic stents market, Indian companies such as Integris Medtech, SMT, Micro Life Sciences, and others have a dominant share of about 60% (based on volume). Integris Medtech is India's second-largest coronary stent manufacturer by sales volume for Fiscal 2025, holding an estimated 22.0% market share in DES used in percutaneous coronary intervention. The company is the first and currently the only domestic company in India to offer a US FDA-approved DES. US FDA-approved DES accounted for 30.0% of the overall stent market volumes in India in 2024, remaining 50.0% CE approved and 20.0% low-cost stents. Moreover, Integris Medtech's vivo ISAR Polymer-Free Sirolimus Eluting Stent, the world's longest studied drug-eluting stent[35] and it is the world's first company to have two DES platforms, VIVO ISAR™ and Yukon Choice, each backed by 10-year clinical safety and efficacy data. Vivo ISAR™ is the world's first dual-drug, polymer-free sirolimus-eluting stent, combining a microporous cobalt-chromium scaffold with a proprietary excipient matrix of sirolimus, probucol, and shellac resin.

[33] Journal of the American College of Cardiology, Asia
[34] Economic and Political Weekly, Vol. 59, Issue No. 35, 31 Aug 2024
[35] Journal of American College of Cardiology; Vol. 76 No. 2

Exhibit 4.9: Share of DES by Volume, 2024



Source: Frost & Sullivan

5. Overview of the Global Clinical Diagnostics Market

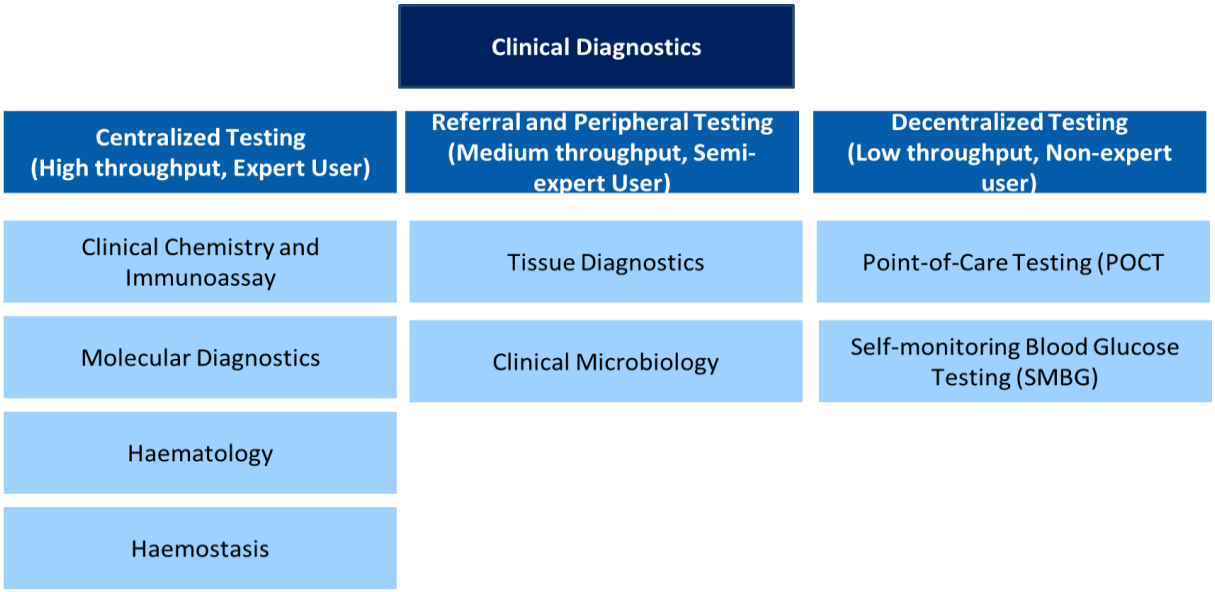
The landscape of clinical diagnostics is evolving, particularly in the wake of the COVID-19 pandemic, which has highlighted the importance of flexible and accessible testing models. The testing models of clinical diagnostics are centralized testing, decentralized testing, and referral/peripheral testing.

- **Centralized testing** refers to the traditional model where laboratory tests are conducted in a single, well-resourced laboratory, typically located in hospitals or specialized facilities. This model allows for economies of scale, as it consolidates resources, expertise, and equipment in one location, ensuring high-quality testing and results. It is particularly effective for complex tests that require specialized equipment and expertise, such as molecular diagnostics for infectious diseases.

- **Referral testing** involves sending samples from peripheral sites (e.g., clinics, outpatient facilities) to centralized laboratories for analysis. This model combines elements of both centralized and decentralized testing. Referral testing can optimize resource use by allowing peripheral sites to handle routine or non-urgent tests while reserving centralized facilities for more complex analyses.

- **Decentralized testing,** also known as point-of-care testing (PoCT), involves conducting tests closer to the patient, such as in clinics, pharmacies, or even at home. This model has gained traction due to its potential to enhance accessibility and reduce the burden on centralized laboratories. Decentralized testing allows for rapid clinical decision-making, as results can be obtained in real-time. This model improves patient access to diagnostics, particularly in remote or underserved areas, and can lead to timely interventions that enhance patient outcomes.

Exhibit 5.1: Clinical Diagnostic segments and testing models



Source: Frost & Sullivan

Clinical diagnostics, comprising clinical chemistry, hematology, molecular diagnostics, immunoassays, microbiology, and point-of-care testing (PoCT) segments, plays a central role in disease detection, disease management, treatment monitoring, and outcomes. The most impactful trend in the clinical diagnostics market is the increasing use of Artificial Intelligence (AI) to accelerate and improve patient diagnosis and patient care. For example, AI models enable personalized treatments in oncology by combining clinical data, pathology, imaging, and genetics to provide prognoses with high accuracy. These AI-enabled diagnostic advancements offer new development pathways for more effective and targeted therapies. Companies are integrating AI into medical devices to offer more value-added in terms of better clinician and patient experience, and better treatment outcomes.

Table 5.1: Major Product Segments of Clinical Diagnostics

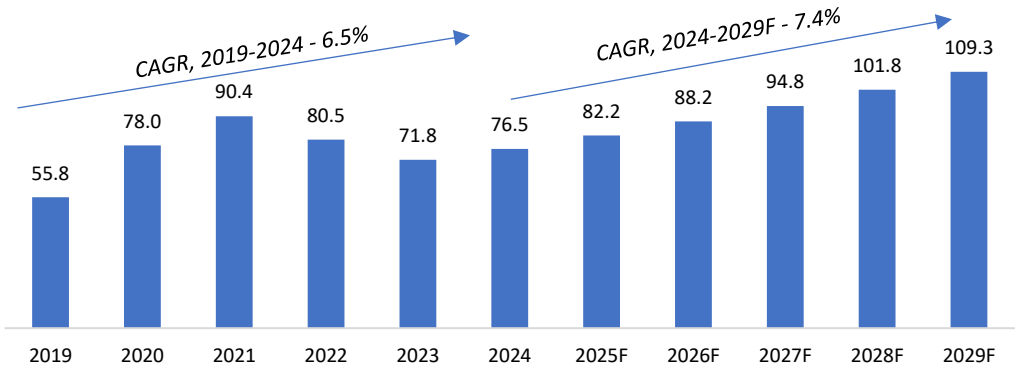
Product Segment	Description [1]
Clinical chemistry	Analyze measurements for assessing organ function, including glucose, lipids, enzymes, hormones, and proteins.
Immunoassays	Detection of molecules linked to immune responses, including allergens and autoimmune markers.
Haematology	Testing of blood components for diagnosing conditions such as anaemia, diabetes, and infectious diseases; includes immunohaematology for transfusion safety and blood gas analysis.
Molecular diagnostics	DNA and RNA analysis for identifying cancers and infectious diseases (e.g., influenza and COVID-19).
Microbiology	Identification of pathogens through culture, identification, and antimicrobial susceptibility testing.
Quality controls	Quality control products and external quality assessment (EQA) programs to ensure ongoing laboratory accuracy and reliability.

5.1. Global Clinical Diagnostics Market

A rise in the ageing population, the prevalence of chronic diseases, increased access to healthcare, advances in next-generation technology, growing focus on prevention, and rising demand for personalized medicine/ tailored diagnostics and treatments continue to drive the growth of the clinic diagnostics market, which continues to enable improved healthcare delivery through disease detection, management, and treatment monitoring.

Further, the market will also be propelled by the expansion of healthcare infrastructure, particularly in emerging markets, and the growing trend towards automation in laboratories.

Exhibit 5.2: Global Clinical Diagnsotics Market (USD Billion), 2019-2029F



Source: Frost & Sullivan

The overall global clinical diagnostics market value was valued at USD 76.5 billion in 2024. The market with positive growth promotion is expected to reach USD 109.3 billion by 2029. While the COVID-19 pandemic highlighted the critical nature of diagnostic capabilities, including molecular diagnostics and point-of-care testing (PoCT), it also paved the way for innovations and increased investments in the market, accelerating the adoption of molecular diagnostics, PoCT, and digital health technologies. The market is expected to continue its positive outlook with a 7.4% CAGR growth between 2024 and 2029, in comparison to 6.5% growth between 2019 and 2024, primarily driven by advancements in genomics, integration of artificial intelligence in the segment, and the growing shift toward preventive healthcare, increasing applications of artificial intelligence in diagnostics segments and procedures.

Lab automation is also increasingly becoming a major growth driver for the clinical diagnostics market. With increasing access to healthcare, higher patient volumes are requiring healthcare providers to deliver faster and more accurate diagnoses to improve patient outcomes. This has led to a pronounced shift in the clinical diagnostics market over the last 5 years, pushing the market more towards lab automation. Lab automation tools such as Siemens Healthineers' next generation hematology analyzers, the Atellica HEMA 570 and Atellica HEMA 580, help to streamline workflow, reduce human error, and lower turnaround time, thereby enabling more extensive testing capabilities and driving increased demand for the clinical diagnostics market.

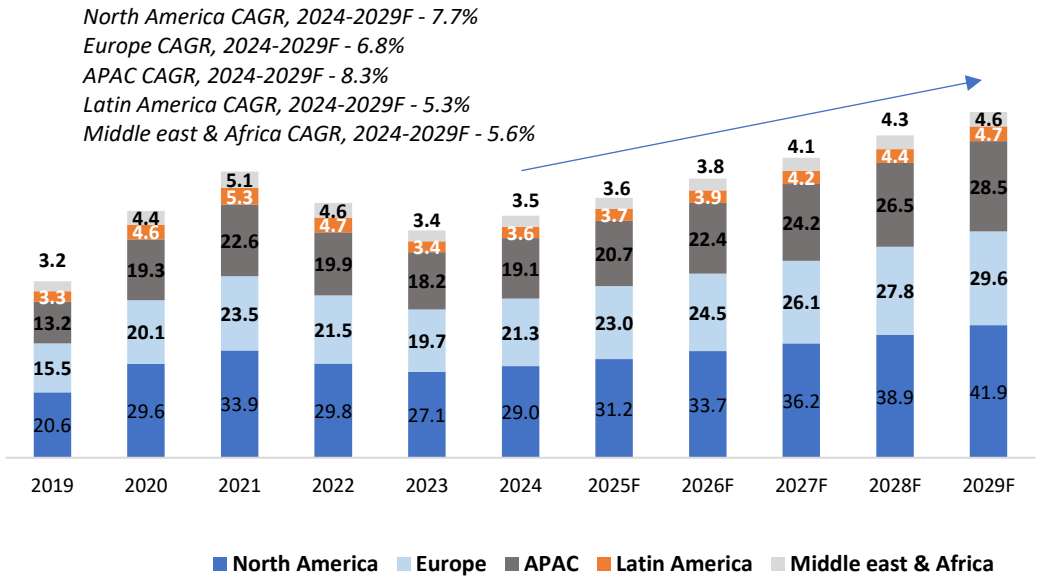
The integration of AI in diagnostics has profound implications, not just in improving disease diagnosis but in transforming patient care as a whole. AI enables medical professionals to create more personalized and effective treatment plans, thereby enhancing the overall healthcare experience for patients. In 2024, numerous real-world examples demonstrate the success of AI-driven treatment plans in improving patient care. In oncology, for instance, AI models that combine clinical data, pathology, imaging, and genetics have enabled more accurate prognoses and personalized cancer treatments. These advancements represent a significant leap forward in precision medicine, offering hope for more effective and targeted therapies.

The number of chronic disease cases, including cancer, cardiovascular diseases, diabetes, and respiratory diseases, continues to rise and increases the demand for diagnostics and diagnostic services. This rise in chronic diseases is also now spread across the age spectrum. For example, the WHO estimates that around 400,000 children between the ages of 0-19 are diagnosed with various forms of cancer every year, while about 17 million people between the ages of 0-70 lose their lives to non-communicable diseases (NCDs). With other factors such as aging and lifecycle contributing to the rise in the number of chronic illnesses, healthcare systems become increasingly reliant on diagnostic tests to detect, monitor, and guide treatment strategies, thus driving the clinical diagnostics market.

5.1.1. Global Clinical Diagnostic Market by Regions

Overall, North America and Europe maintain dominance, while Asia-Pacific, led by China and India, represents the fastest-growing frontier. Emerging trends such as PoCT, AI-driven diagnostics, and personalized medicine are reshaping the competitive landscape, pushing companies towards technological innovation, regional expansion, and strategic collaborations to stay ahead in the evolving global clinical diagnostics market.

Exhibit 5.3: Clincial Diagnostic Market by Geographies (USD Billion), 2019-2029F



Source: Frost & Sullivan

The clinical diagnostics market in North America is set to grow from USD 29.0 billion in 2024 and reach USD 41.9 billion by 2029 at a CAGR of 7.7%. In countries such as the US, the healthcare cost for chronic disease treatment continues to rise sharply. The region's market is expected to grow at a lower rate compared to the APAC region.

Europe's clinical diagnostics industry was valued at USD 21.3 billion in 2024 and is set to grow at a steady 6.8% CAGR to reach USD 29.6 billion in 2029, primarily driven by the increasing awareness of point-of-care testing, access to and increased accuracy of in-vitro diagnostic tests, growing awareness, and adoption of clinical diagnostics. Similar to North America, the region's market is expected to grow at a lower rate compared to the APAC region.

The clinical diagnostics market in the APAC region is set to grow from USD 19.1 billion in 2024 to USD 28.5 billion by 2029 at a CAGR of 8.3%. The clinical diagnostics market in the Asia-Pacific (APAC) region is experiencing significant growth, driven by a confluence of factors, particularly in emerging economies like India, China, Indonesia, and Vietnam. Point-of-care (POC) diagnostics and Telehealth are gaining popularity, particularly in remote areas, due to

their ability to provide rapid and convenient testing. Further, the Government's focus on expanding healthcare access and improving disease management in countries such as India and China is driving market growth. For instance, PPP models have been employed in the Indian diagnostics industry to facilitate the provision of diagnostic services in rural and remote areas, upgrade existing facilities, and foster the development of new diagnostic technologies. Similarly, the Government of India has established National, State, and District-level NCD Cells under the National Programme for Prevention and Control of Non-Communicable Diseases (NP-NCD) for early diagnosis, treatment, and follow-up. India is solidifying its role as a key player in the MedTech industry, fueled by a focus on cost-effective innovation and local manufacturing initiatives.

The clinical diagnostics market in the rest of the world regions (Latin America and the Middle East, and Africa) is expected to witness modest growth (5.3% and 5.6%). The combined value of the clinical diagnostics market in these regions is expected to grow from 7.1 billion in 2024 to 9.3 billion in 2029.

5.1.1.1. End-User Ecosystems

The clinical diagnostics market is highly fragmented, with various end-users playing a pivotal role in delivering diagnostic solutions across different healthcare settings. The market is shifting toward greater digital integration, automation, and decentralized testing models, expanding access to diagnostics beyond traditional hospital laboratories.

The hospital segment dominates the end-user segments with the highest market share. This is attributable to growing clinical diagnostics demand in hospital-based medical labs for disease diagnosis, blood cell counts, detecting illegal drug use, protein analysis, blood typing, and monitoring therapeutic drug levels, along with detecting the presence of antibodies. The growing demand for emergency facilities and the increasing incidence of emergencies requiring immediate attention, such as road accidents and sudden cardiovascular events. Furthermore, with the increasing number of patients suffering from lifestyle and chronic diseases, specialized outpatient clinics are registering significant growth. These clinics offer targeted care for specific conditions, allowing for more personalized treatment plans and improved outcomes.

The home care settings segment is anticipated to expand at a rapid pace over the forecast period. The segment is driven by several key factors, including the rise of chronic diseases, the aging population, technological advancements, and the desire for more convenient and accessible healthcare options. This market is poised to expand substantially over the next few years, offering innovative solutions that allow patients to manage their health conditions at home, thereby reducing the need for frequent hospital visits and lowering healthcare costs. In addition, innovations in home healthcare, including the integration of AI into home diagnostic devices, offer advanced features such as real-time analysis of results, personalized recommendations, and early disease detection capabilities.

Exhibit 5.4: End-user segments in clinical diagnostics

5.1.2. Global Clinical Diagnostics Market by Segments

The clinical diagnostics market's transformation is fueled by technological innovations and an increasing focus on personalized healthcare. This has led to the dynamic growth of segments such as molecular diagnostics and PoCT, which are enabling healthcare providers to address global health challenges.

Clinical chemistry and immunoassay, a major and well-established segment in clinical diagnostics, is valued at USD 23.7 billion in 2024, and it is estimated to grow at a CAGR of 7.0% to reach USD 33.2 billion in 2029. Increased prevalence of diabetes and cardiovascular disorders is also driving the growth of the clinical chemistry and immunoassay product segment, in addition to advancements in automation and AI-driven assay technologies. For example, high-sensitivity troponin tests enable early and accurate detection of myocardial infarctions.

Molecular Diagnostics, with an estimated market size of USD 15.7 billion in 2024, is set to rise at a 9% CAGR and is projected to reach USD 24.1 billion by 2029. It is the fastest-growing product segment within the clinical diagnostics market and is mainly propelled by the demand for rapid and precise disease detection, especially in infectious diseases and oncology therapeutic areas. With technologies such as PCR, NGS, and liquid biopsy finding increasing applications in personalized care, this segment will play a big part in transforming patient care.

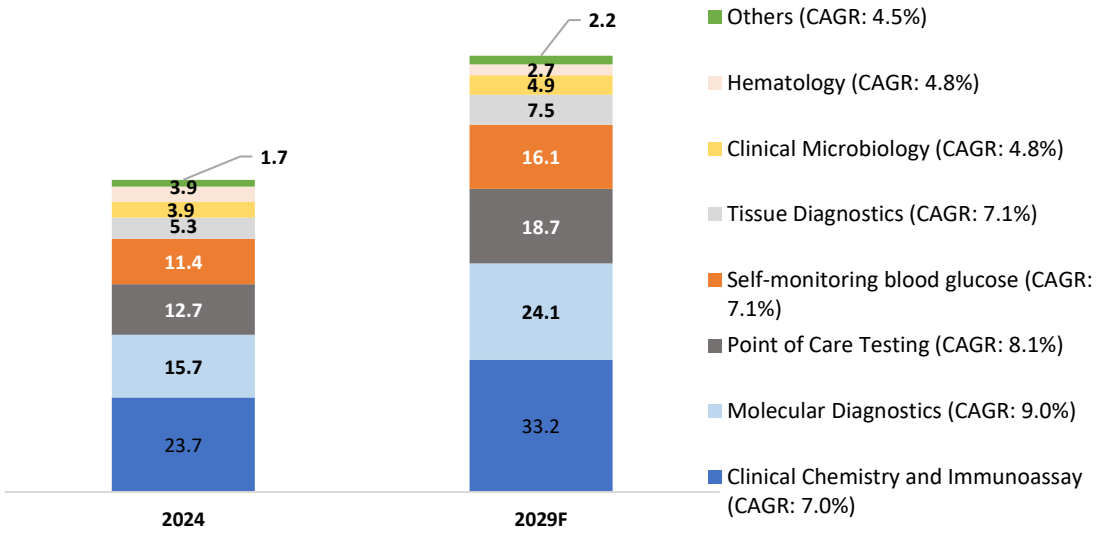
The PoCT segment closely follows the molecular diagnostics segment in terms of projected growth, from a market value of USD 12.7 billion in 2024 to USD 18.7 billion by 2029, growing at a CAGR of 8.1%. While the COVID-19 pandemic reshaped the foundational growth of PoCTs, the segment continues to gather momentum owing to increasing demand for personalized medicine, a shift toward decentralized healthcare, and the immediacy of diagnostic results. End-users are increasingly drawn towards innovations in infectious disease detection, such as handheld devices and home-based test kits, due to their convenience, further propelling the growth of the product segment. The integration of telehealth and remote patient monitoring (RPM) into healthcare systems has significantly influenced the adoption of point-of-care testing (PoCT). Telehealth and RPM facilitate access to healthcare services, particularly in remote or underserved areas. By enabling patients to conduct tests at home or in local clinics, PoCT becomes more accessible, reducing the need for travel to centralized laboratories.

The escalating global incidence of diabetes is driving the self-monitoring of blood glucose (SMBG) market. In the SMBG market, the adoption of continuous glucose monitoring (CGM) systems, due to their non-invasive technology and ease of use, continues to rise. In addition, AI-driven data analytics providing personalized diabetes management solutions are also aiding in improving patient outcomes. Overall, the SMBG segment is growing at a robust rate of 7.1% CAGR from USD 11.4 billion in 2024 to USD 16.1 billion in 2029, fueled by the increasing prevalence of diabetes around the globe.

The advanced tissue diagnostic segment is a necessity to manage the rising cancer burden globally. As the incidences of cancer rise at a sharp rate, advanced technologies such as digital pathology and AI-powered image analysis are being positioned as aids for pathologists in terms of increasing diagnosis accuracy and reducing diagnosis lead time. Driven by the latest advancements, such as digital pathology, the tissue diagnostics segment is set to grow from USD 5.3 billion in 2024 to USD 7.5 billion by 2029 at a CAGR of 7.1%.

Global challenges such as antimicrobial resistance and emerging pathogens are driving the need for innovative and advanced microbiology diagnostics. Tools such as automated culture systems and mass spectrometry-based microbial identification are enabling rapid and accurate pathogen detection, while high-throughput hematology analyzers and integrated flow cytometry are propelling the hematology segment. However, the microbial diagnostics and hematology segment is expected to only have a moderate growth of 4.8% as advanced technologies such as Molecular Diagnostics and PoCT are set to gain prominence in the clinical diagnostics market in the forecast period. The clinical microbiology segment is estimated to grow from USD 3.9 billion in 2024 to USD 4.9 billion in 2029, and the Hematology segment is estimated to grow from USD 2.2 billion in 2024 to USD 2.7 billion in 2029.

Exhibit 5.5: Clincial Diagnostics, Market size and growth by segments, 2024 and 2029F

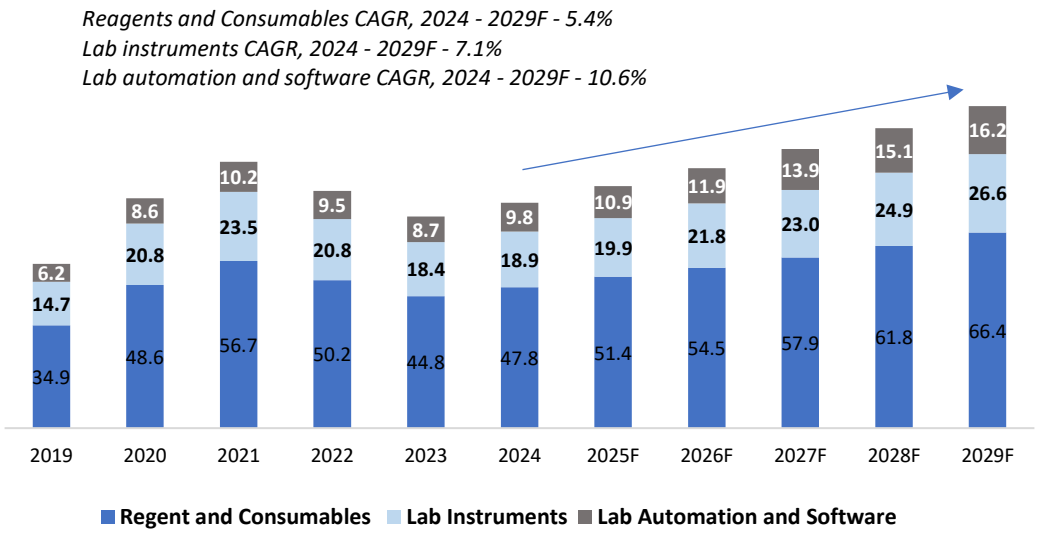


Source: Frost & Sullivan

5.1.3. Global Clinical Diagnostics Market by Product

The clinical diagnostic market can further be classified based on different product groups, as elaborated below.

Exhibit 5.6: Clincial Diagnostic Market by Product (USD Billion), 2019-2029F



Source: Frost & Sullivan

- Reagents and consumables, the largest segment, are anticipated to grow from USD 34.9 billion in 2019 to USD 66.4 billion by 2029, at a CAGR of 5.4% (2024-2029F). The segment's consistent growth is attributed to the increasing volume of diagnostic tests, the need for repeat purchases, and the expanding role of molecular diagnostics and immunoassays.

- Laboratory instruments accounted for USD 14.7 billion in 2019, with growth projected to reach USD 26.6 billion by 2029, driven by a 7.1% CAGR (2024-2029F). The demand for advanced diagnostic equipment, including high-throughput analyzers, imaging-based diagnostic systems, and point-of-care testing devices, is fueling the expansion of this segment.

The lab automation and software segment, though the smallest, is the fastest-growing, rising from USD 6.2 billion in 2019 to USD 16.2 billion by 2029, supported by a 10.6% CAGR (2024-2029F). The increasing adoption of AI-driven diagnostic platforms, automated workflow solutions, and integrated laboratory information systems (LIS) is driving growth in this category.

5.1.4. Region-specific Growth Drivers

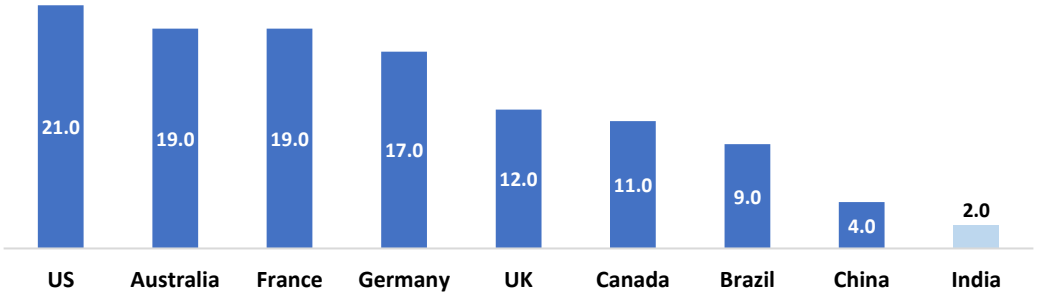
Emergence of diagnostic chains

The clinical diagnostics market in India and the Asia-Pacific (APAC) region is witnessing a rapid shift as diagnostics companies are moving away from being standalone laboratories to organized diagnostic chains. This trend is being driven by increasing urbanization, health awareness, and increased per capita income of the general population. Leading players such as Dr. Lal PathLabs, SRL Diagnostics, Metropolis Healthcare (India), and Pathology Asia Holdings (Singapore) are expanding their reach regionally and nationally through acquisitions and franchising. For instance, from 2019 to 2024, Dr. Lal Path Labs has shown significant revenue growth from USD 145.8 million to USD 262.9 million (CAGR of 12.5%), which can be indicative of market share expansion. Similarly, Metropolis Healthcare (India) has shown significant revenue growth from USD 54.4 million in 2015 to USD 144.4 million in 2024 (CAGR of 11.5%). By creating diagnostic chains, these companies can tap into economies of scale as they present attractive offerings such as standardized testing protocols and home sample collection, which are focused on affordability and

accessibility, making them the preferred choice of diagnostic partner for hospitals and corporate organizations. In India, the Ayushman Bharat Health Infrastructure Mission (ABHIM) and the digital health ecosystem are enabling the diagnostic chains to expand from Tier-1 cities to Tier-2 and Tier-3 cities, where access to quality diagnostics has historically been limited, further ensuring increased demand for clinical diagnostics.

The clinical diagnostics market in emerging countries such as India and China is underpenetrated compared to developed markets such as the US, Australia, and France. The number of yearly diagnostic tests per capita in India and China is less than 5, compared to more than 20 in the US and more than 10 in countries such as Germany and France.

Exhibit 5.7: Diagnostic Test per Year per Capita, Select Countries, 2023



Source: Frost & Sullivan

Government Initiatives

Government policies and initiatives across India and APAC are playing a pivotal role in shaping the growth of the diagnostics market. In India, initiatives like Ayushman Bharat, the National Digital Health Mission (NDHM), and Production Linked Incentive (PLI) schemes for medical devices are fostering domestic manufacturing and investment in diagnostics. The initiatives, along with the government's push for universal healthcare coverage (UHC), are also driving demand for cost-effective testing solutions in rural and semi-urban areas.

India's National TB Elimination Programme (NTEP) aims to eradicate tuberculosis by 2025, employing active case finding and widespread diagnostic testing. The "Nikshay Mitra" initiative encourages community support for TB patients, providing nutritional and social assistance. The program prioritizes early diagnosis and free treatment, with a focus on vulnerable populations and drug-resistant TB. Recent campaigns, like the 100-day TB elimination initiative, are designed to accelerate progress through enhanced detection and treatment.

In Southeast Asia, especially in countries such as Indonesia, Thailand, and Vietnam, the governments are turning towards public-private partnerships (PPP) in a bid to modernize the healthcare and diagnostic infrastructure. The Healthy China 2030 policy, with its significant investment in genomics, AI-driven diagnostics, and molecular testing, while Japan continues to promote early disease detection through precision medicine and advanced imaging technologies. These strategic government interventions are ensuring sustained growth in the clinical diagnostics market while fostering innovation and accessibility.

The Philippines' Newborn Screening (NBS) Program aims to detect congenital metabolic disorders early, enabling timely intervention. The program is mandated by Republic Act 9288 and covers several conditions, including congenital hypothyroidism and phenylketonuria. Efforts are ongoing to strengthen the program through increased public awareness and improved laboratory capacity.

Malaysia's National Health Screening Initiative (NHSI) aims to promote early detection and prevention of NCDs. The program emphasizes proactive health assessments for various age groups, focusing on conditions like diabetes, hypertension, and cancer. NHSI utilizes a network of public health clinics and mobile screening units to reach diverse populations, including those in rural areas.

The Singapore government regularly outlines five-year RIE plans (currently RIE2025). These plans allocate significant funding towards research and development in key areas, including biomedical sciences, health and wellness, and advanced manufacturing. Clinical diagnostics, especially those with high impact potential (e.g., for prevalent diseases in Asia, precision medicine), are often prioritized. Agency for Science, Technology and Research (A*STAR) plays a central role, with various institutes and platforms conducting cutting-edge research in genomics, molecular biology, and diagnostics. The Diagnostics Development Hub (DxD Hub), established in 2014 under A*STAR, is a national platform specifically designed to bridge the gap in the productization of diagnostic products and services. It de-risks the adoption of publicly funded diagnostic intellectual properties by the industry.

5.2. Key trends in the Diagnostic industry

Growing adoption of point-of-care testing (PoCT)

PoCT products have been a transformational part of the clinical diagnostics market over the last 5 years, with their ability to enable rapid and convenient testing in a healthcare setting, remote location, or at home, providing immediate results, allowing for faster decision-making, treatment initiation, and treatment outcomes.

The COVID-19 pandemic accelerated the demand for PoCT innovations, with innovations focusing on faster turnaround times, and the trend has only extended to other infectious diseases, such as influenza, and chronic disease management, such as diabetes and cardiovascular diseases, in the years after. Clinical diagnostic companies are investing increasingly in PoCT innovations, with products focusing on affordability and ease of use.

Another aspect of the COVID-19 pandemic that has been influential for the PoCT sector is the rise of telemedicine. The shift towards decentralized healthcare has required rapid, on-site diagnostics outside clinical settings and has led to the increased adoption of PoCT. The global market for PoCT was valued at USD 12.7 billion in 2024 and is expected to grow at a CAGR of 8.1% to reach USD 18.7 billion by 2029, fuelled by technological advances such as miniaturization, enhanced accuracy, and efficiency, reducing the reliance on diagnostic centers/laboratories. The integration of smartphone-based diagnostics and implantable biosensors is set to reshape the landscape, offering both physicians and patients real-time monitoring and data-driven insights for more personalized healthcare.

Growth in Molecular Diagnostics

Besides PoCT, Molecular diagnostics (Molecular Diagnostics) also played a critical role during the COVID-19 pandemic in pathogen detection and antimicrobial resistance screening. The COVID-19 pandemic, while initially causing a massive surge in demand for SARS-CoV-2-specific molecular diagnostics, has fundamentally reshaped the landscape and driven sustained demand in the broader molecular diagnostics market. Factors such as the acceleration of personalized medicine and genomics, an elevated focus on infectious disease preparedness and surveillance, and increased awareness and acceptance of molecular testing have propelled the market. Currently, over 50% of the molecular diagnostics market is focused on infectious disease testing. Molecular Diagnostics continues to be one of the fastest-growing areas in infectious disease identification as it employs diagnostic techniques such as DNA microarray analysis, mass spectrometry, and nucleic acid amplification. With the clinical diagnostics market being boosted by laboratory automation and workflow efficiency, molecular diagnostics will be utilized for applications across multiple therapeutic areas. Molecular Diagnostics players are moving away from classical and time-consuming methods requiring pathogen cultures towards effective, rapid diagnostics.

Further, Molecular Diagnostics is also set to play an important part in the advent of precision medicine, which is built on technologies such as next-generation sequencing (NGS), polymerase chain reaction (PCR), CRISPR, and liquid biopsy. These advanced tools allow clinicians to detect novel biomarkers in blood samples, enabling early cancer detection and treatment monitoring with minimal invasiveness. The integration of AI in molecular diagnostics is expected to further enhance market growth, which is expected to grow at a 9.0% CAGR from USD 15.7 billion in 2024 and reach a market value of USD 24.1 billion by 2029.

Rising awareness and acceptance of personalized medicine and companion diagnostics

Another segment that is experiencing a growth surge is the companion diagnostics market. The increased demand for personalized medicine has also paved the way for companion diagnostics (CDx). Oncology was one of the biggest segments to utilize CDx effectively. With an increasing focus on biomarker-driven drug development by pharmaceutical companies, CDx plays a critical role in identifying the right patient populations for targeted and personalized therapies. For example, physicians prescribe drugs such as Keytruda and Herceptin to patients only after biomarker testing. As personalized approaches expand beyond oncology into neurology, cardiology, and autoimmune diseases, CDx is set for a surge in growth, especially in the advanced economies, owing to pricing and access. Multiple studies indicate that the probability of a lead compound moving from the clinical phase to the market is very low. Yet, the use of disease-specific biomarker data in clinical trials for patient recruitment indicates a sixfold increase in trial success and a reduction in clinical trial costs. In addition, regulatory bodies such as the FDA and EMA push for the utilization of companion diagnostics in the drug approval process. The CDx segment is poised for sustained growth, reshaping patient care and treatment outcomes.

Increasing Adoption of Artificial Intelligence and Machine Learning in Diagnostics

AI and ML technologies are increasingly being utilized in clinical diagnostics to analyze complex medical data, identify patterns, and support clinical decision-making. These technologies leverage vast datasets, including electronic health records (EHRs), medical imaging, and genomic data, to improve diagnostic accuracy and speed. By automating routine diagnostic tasks and improving operational efficiencies, AI can help reduce healthcare costs. This is particularly relevant as healthcare systems seek to manage rising expenses while maintaining high-quality care.

5.3. Competitive landscape in the Clinical Diagnostics Market

The clinical diagnostics market is witnessing intense competition driven by rapid technological advancements, regulatory shifts, and evolving patient needs. The competitive landscape of the market is driven by a differentiated strategy between the global and regional players. While leading global companies such as Roche, Abbott, and Siemens continue to focus on expanding their portfolio and strengthening their distribution networks, regional players, especially in the Asia-Pacific region, are focused on volume-based gains and offer cost-effective and tailored solutions to emerging markets.

The industry is experiencing consolidation through mergers and acquisitions, as companies seek to expand their capabilities in molecular diagnostics, point-of-care testing (PoCT), and AI-driven diagnostics. Startups and mid-sized firms are making notable inroads with innovations in personalized medicine, liquid biopsy, and automation-driven lab efficiencies.

Price pressures, stringent regulatory requirements, and the demand for faster, more accurate diagnostics are shaping competitive dynamics. Additionally, government initiatives, particularly in India and China, are fostering domestic growth and reducing reliance on imported diagnostic technologies. With increasing demand for decentralized testing, competition is shifting toward accessibility, affordability, and technological integration, making the landscape more dynamic than ever.

Smaller OEMs typically don't have the vast financial and human resources of larger corporations to build extensive sales, marketing, and distribution networks from scratch, especially across diverse geographies. They need local/regional partners to reach the end-market, which enables rapid market expansion with low capital investment, offers diversification and flexibility, and helps to leverage customer touchpoints. Local partners have existing relationships with hospitals, clinics, reference labs, and individual practitioners in their specific region. Local partners provide invaluable feedback on market needs, customer preferences, competitive activities, and potential product improvements, helping the OEMs to adapt and innovate.

The consolidation of distribution channels in clinical diagnostics is a natural evolution driven by the demands for efficiency, cost reduction, and integrated solutions across the healthcare value chain. As hospitals and health systems merge, they prefer to deal with fewer, larger vendors and distributors. They seek to simplify procurement and reduce administrative overhead. Healthcare providers increasingly want a single point of contact for a broad range of diagnostic products and services, including reagents, instruments, consumables, and even IT solutions. Diagnostic manufacturers, especially large ones, benefit from fewer, larger distributors that can handle higher volumes and cover wider geographic areas more efficiently. Moreover, larger distributors often have established networks and relationships in diverse markets, helping manufacturers penetrate new regions or customer segments more quickly.

Table 5.2: Competitive Landscape of select companies in Clinical Diagnostics

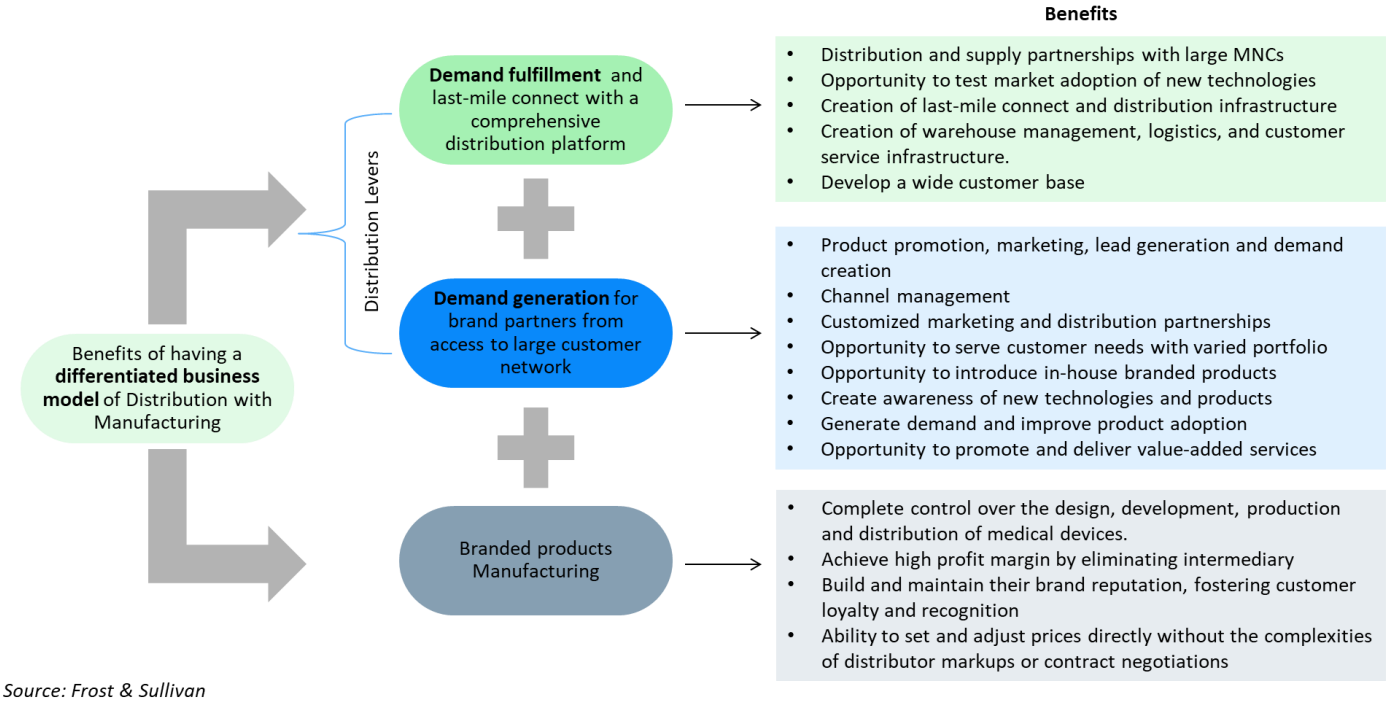
Company	Headquarters	Operational Footprint	Clinical Diagnostic Product Portfolio
Roche Diagnostics	Basel, Switzerland	North America, Europe, APAC, and RoW markets	Molecular diagnostics, immunoassays, clinical chemistry, digital pathology
Abbott Laboratories	Illinois, USA	North America, Europe, APAC, and RoW markets	Point-of-care testing, immunoassays, haematology, and molecular diagnostics
Thermo Fisher Scientific	Massachusetts, USA	Global reach with operations in over 50 countries	Clinical chemistry, molecular diagnostics, microbiology, and laboratory automation
Siemens Healthineers	Erlangen, Germany	Strong presence in Europe, North America, and APAC	Clinical chemistry, hematology, immunoassays, and molecular diagnostics
Danaher Corporation	Washington, D.C., USA	Global presence with operations in over 60 countries	Immunoassays, microbiology, molecular diagnostics, and blood screening
Sysmex Corporation	Kobe, Japan	Strong presence in APAC, increasing presence in	Hematology analyzers, coagulation testing, and urinalysis

		North America and Europe	
bioMérieux	Marcy-l'Étoile, France	Based out of Europe, increasing presence in North America and APAC	Microbiology, immunoassays, and molecular diagnostics
Becton, Dickinson & Co. (BD)	New Jersey, USA	Strong network in North America and Europe, growing in APAC	Microbiology, immunoassays, molecular diagnostics, and blood collection systems
Qiagen	Hilden, Germany	Strong European presence with North American and Asian markets	Molecular diagnostics, sample preparation, and PCR-based testing
Integris Medtech	Delhi NCR, India	India, Europe, Latin America, APAC	Immunodiagnostics, Clinical chemistry, Hematology, Microbiology, Molecular Diagnostics, and other clinical diagnostics
Transasia Bio-Medicals	Mumbai, India	Presence in over 100 countries with manufacturing units in India and abroad.	Manufactures diagnostic instruments and reagents for biochemistry, hematology, immunology, and molecular diagnostics.

Source: Frost & Sullivan. Note: Operational footprint is not limited to Clinical Diagnostic products

5.4. Benefits of Integrated Distribution and Manufacturing Business Model in Clinical Diagnostics

Exhibit 5.8: Differentiated model of integrated multi-brand distribution/commercialization platform with branded products manufacturing



Source: Frost & Sullivan

The combination of manufacturing with a multi-brand distribution and commercialization platform offers significant advantages to companies in the clinical diagnostics industry. This model enables companies to not only maintain greater control over their product lines, supply chains, and overall business operations but also offers the potential to leverage the distribution network for various demand generation partnerships with OEMs and introduce other value-added services for customers. Among leading clinical diagnostic companies, Integris, the largest scientific lab solutions company in Southeast Asia, has a large integrated distribution and manufacturing model. The company's clinical diagnostic product universe is highly diversified, addressing more than 35 major product segments across clinical diagnostics and scientific lab solutions (Life Sciences and Analytical Sciences applications). The company offers clinical diagnostic solutions (immunodiagnostics, clinical chemistry, hematology, molecular diagnostics, and others) and scientific lab solutions (cell biology, antibodies, genomic, proteomic, and others).

6. Overview of the Scientific Lab Solutions Market

The scientific lab solutions market is a rapidly growing market encompassing a wide range of products, technologies, and services catering to industries such as healthcare, pharmaceuticals, biotechnology, food safety, etc. The market is currently driven by several technological advancements in the areas of AI, data analytics, and lab automation, which are enabling laboratories to become more efficient by moving away from manual workflows to digitally enabled workflows and systems. The growing prevalence of chronic diseases and the emergence of personalized therapies are fueling the growth of precision medicine and molecular diagnostics, which in turn are driving demand for advanced scientific lab solutions such as sequencing, liquid handling, lab informatics, etc.

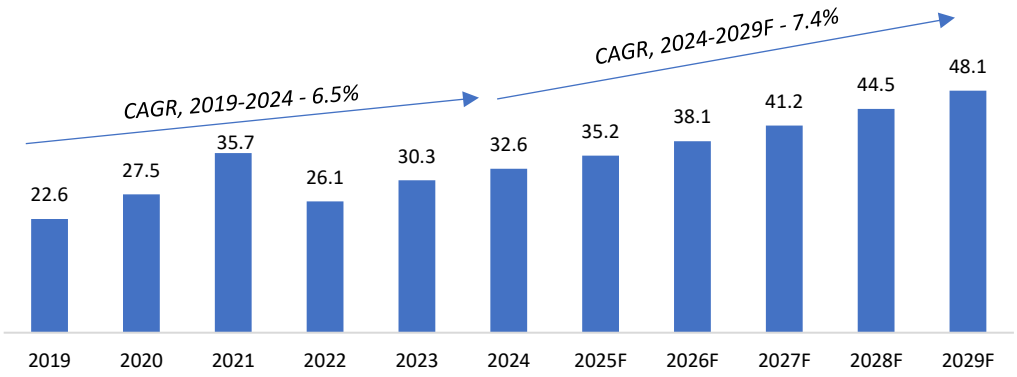
6.1. Global Scientific Lab Solutions Market

The scientific lab solutions market is rapidly evolving, driven by advanced diagnostics, automation, and AI, enhancing efficiency and precision for several different industries. With rising R&D investments, regulatory compliance needs, and lab outsourcing trends, the market is set for sustained global growth.

The global scientific lab solutions market is being driven by advancements in automation, artificial intelligence (AI), and digital lab integration. Laboratories across industries, such as healthcare, pharmaceuticals, biotechnology, and industrial testing, are increasingly adopting and relying on next-generation sequencing (NGS), robotic liquid handling, and AI-driven lab informatics to enhance efficiency, accuracy, and scalability.

Moreover, the COVID-19 pandemic significantly accelerated the market growth of clinical scientific lab solutions by creating an unprecedented and immediate demand for diagnostic testing. This surge in demand had several key impacts. The crisis spurred rapid innovation in diagnostic technologies. Molecular diagnostics, particularly PCR, moved into the spotlight, and there was accelerated development of new, faster, and more accessible testing methods, including point-of-care (POCT) and at-home testing kits. This pushed labs to adopt automation, robotics, and digital solutions to handle the high throughput and improve turnaround times. The pandemic increased the public awareness of diagnostics and has led to a greater acceptance and demand for testing, not just for infectious diseases but also for general health monitoring, preventive care, and chronic disease management.

Exhibit 6.1: Global Scientific Lab Solutions Market (USD Billion), 2019-2029F



Source: Frost & Sullivan

Driven by the growing demand for precision testing, technological advancements, and innovative solutions to aid research and diagnostics, the global scientific lab solutions market is valued at 32.6 billion in 2024. With a growth rate of 7.4% CAGR between 2024 and 2029, the market is set to reach 48.1 billion by 2029. The market's sustained growth is mainly expected to come from innovations in high-performance lab instruments and workflow automations, in addition to increasing demand for advanced diagnostics, the growth of the contract research organizations (CROs) market, and increasing year-on-year pharmaceutical R&D spend. As more regulatory reforms are being implemented in terms of more stringent compliance requirements, there is a heightened demand for automated workflows to ensure improved traceability and enhanced quality control.

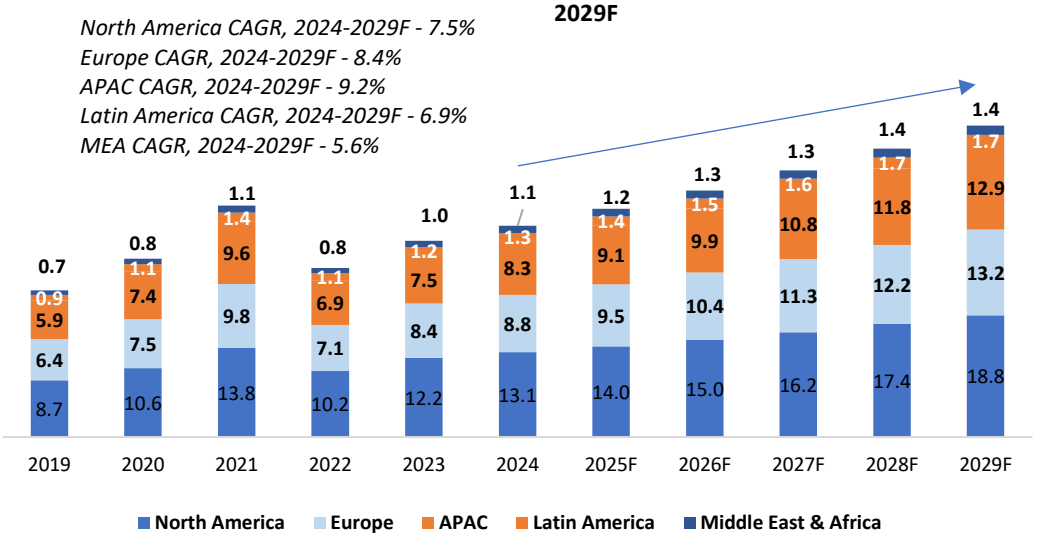
With continuous technological advancements and a growing need for efficient, scalable, and cost-effective laboratory solutions, the global scientific lab solutions market is poised for sustained growth in the coming years. Further, there is also growing interest in sustainability initiatives, leading to a strong shift toward sustainable lab practices, leading to the adoption of energy-efficient instruments in addition to advanced technologies.

6.1.1. Global Scientific Lab Solutions Market by Regions

The global scientific lab solutions market is characterized by diverse regional trends influenced by economic, technological, and healthcare-based factors. Understanding these regional dynamics is critical for companies looking to capitalize or thrive in the evolving landscape of the scientific lab solutions market.

North America accounts for about 40% share in 2024. The region's lab solution market is valued at USD 13.1 billion in 2024, and it is estimated to grow at a lower CAGR of 7.5% compared to the APAC region, to reach USD 18.8 billion in 2029. The European region accounts for about 27% share. The region's lab solution market is valued at USD 8.8 billion in 2024, and it is estimated to grow at a CAGR of 8.4% to reach USD 13.2 billion in 2029.

Exhibit 6.2: Global Scientific Lab Solutions Market by Geographies (USD Billion), 2019-2029F



Source: Frost & Sullivan

The Asia-Pacific (APAC) region accounts for a 25% share in the global scientific lab solutions market with a market value of USD 8.3 billion in 2024 and is estimated to reach USD 12.9 billion in 2029 at a high CAGR of 9.2% compared to other regions such as North America and Europe. The APAC region is experiencing a rapid expansion in the scientific lab solutions market, aided by increased access to healthcare, insurance coverage, and economic growth. India, one of the leading countries in the APAC scientific lab solutions market, is expected to experience the fastest growth in laboratory technologies, products, and services owing to its growing healthcare infrastructure, prevalence of chronic diseases, and favorable regulatory environment.

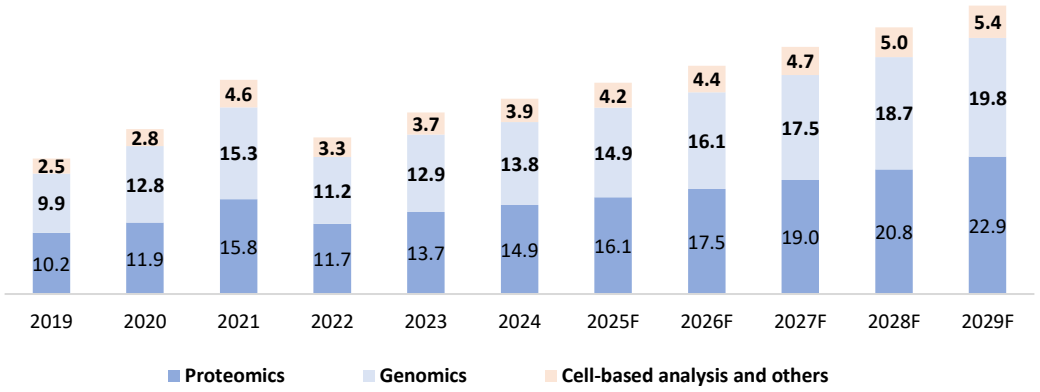
The scientific lab solutions market in the rest of the world regions (Latin America and the Middle East, and Africa) is expected to witness moderate growth. Currently, Latin America, the Middle East, and Africa regions account for a small portion of the scientific lab solutions market, holding a combined share of 7.4% (USD 2.4 billion).

6.1.2. Global Scientific Lab Solutions Market by Technology

The scientific lab solutions market is undergoing rapid transformation, with technological advancements in proteomics, genomics, and cell-based analysis, which are enabling breakthroughs in precision medicine, biomarker discovery, and personalized therapies. Sustained market growth in scientific lab solutions is driven in turn by the demand for precision medicine, drug development, and biomarker research.

Exhibit 6.3: Global Scientific Lab Solutions Market by Technology (USD Billion), 2019-2029F

Proteomics CAGR, 2024 - 2029F - 9.0%
Genomics CAGR, 2024 - 2029F - 7.5%
Cell-based analysis and Others CAGR, 2024 - 2029F - 6.7%



Source: Frost & Sullivan

Proteomics has a major share in the scientific lab solutions market, and it is also the fastest-growing segment. The growth surge is fueled by an increasing focus on the analysis of protein structures and functions by academia and industry. With advancements in technologies such as mass spectrometry, protein microarrays, and high-throughput screening, proteomics has become an indispensable part of drug discovery and biomarker discovery. The increasing adoption of single-cell proteomics and label-free protein analysis, which enables protein expression analysis at the cellular level, is further driving the market growth. The proteomics market is projected to reach a market value of 22.9 billion by 2029 from 14.9 billion in 2024, growing at a CAGR of 9.0%.

While the genomics segment is not expected to grow as fast as the proteomics segment, it is still expected to grow at a high CAGR of 7.5%, from 13.8 billion in 2024 to 19.8 billion in 2029. The growth in the genomics segment is expected to be driven by the widespread adoption of advanced sequencing and gene-editing platforms. The democratization of genomic research, owing to the lowered sequencing costs, has driven its increased applications in disease diagnostics and synthetic biology. Companies such as Illumina and Oxford Nanopore Technologies are pioneering innovations in sequencing that have led to expanded applications for genomics. The increasing application of genomics has also been driven by the need for cloud computing and blockchain for secure genomic data sharing.

Advanced research labs focused on drug discovery and development are reliant on cell-based analysis and platforms. New disease models and preclinical studies are driving the demand for high-content imaging, advanced cell culture technologies, and other technologies. Innovations in cell-based assay platforms and digital pathology continue to shape the lab and research segments, driving growth in cell-based analysis and other related segments. The market for cell-based analysis and other scientific lab solutions is expected to grow from USD 3.9 billion in 2024 to USD 5.4 billion in 2029 at a modest CAGR of 6.7%. The table below sets forth specialized life science research tools for academia and research institutions:

Table 6.1: Major Product Segments of Scientific Lab Solutions	
Product Category	**Description [(1)]**
Cell biology products and instruments	Cell culture consumables (plates, flasks, bottles, media), cell lines and organisms, and key instruments for cellular and molecular studies including microplate readers, imaging systems, and flow cytometers.
Antibodies	Used to detect and quantify proteins through applications like western blotting and immunohistochemistry.
Genomics	Tools for analyzing DNA and RNA structure and function, including next-generation sequencing, PCR, and related methods.
Proteomics	Equipment and reagents for comprehensive protein study, such as chromatography, mass spectrometry, gel electrophoresis, and enzyme-based assays.

6.2. Key Growth Drivers

The scientific lab solutions market is undergoing a significant transformation and evolving with advancements in technology, automation, healthcare demand, outsourcing trends, and regulatory frameworks.

Some of the major growth drivers of the scientific lab solutions market are:

- **Technological advancements:** Labs are modernizing with advanced technologies such as robotic liquid handlers, which can precisely dispense and mix samples in a highly automated, efficient, and accurate manner. Moreover, as the labs produce a huge amount of data with the adoption of technologies, AI-driven data analytics platforms are leveraged to enhance diagnostic accuracy and drive predictive analytics in disease research.
- **Growing healthcare and diagnostic needs:** Increase in the prevalence of chronic diseases and the advent of personalized medicine are driving the demand for lab technologies, products, and services. The growing demand f, or precision medicine is being enabled by advances in technologies such as next-generation sequencing and polymerase chain reaction testing. In addition, CROs and other drug development laboratories are utilizing high-throughput, AI-enabled, and automated screening to accelerate drug discovery.

Increased Pharma R&D investment: The increased investment by biopharma companies in the regenerative medicine therapy area, especially cell and gene therapy, is driving increased demand for advanced technologies, such as the CRISPR (clustered regularly interspaced short palindromic repeats) platform, to enable gene sequencing for the development of therapies for genetic disorders. For instance, as of Q4 2024, there were 4,238 gene, cell, and RNA therapies in development, ranging from preclinical through pre-registration.[36] Roche acquired Poseida Therapeutics in 2024 for approximately USD 1.5 billion to strengthen its CAR-T therapy portfolio. Novartis signed a USD 1.1 billion deal to acquire Kate, a gene therapy biotech company, in 2024.

Increased investment in lab infrastructure: The Growing need to reduce operational costs and increase research efficiency is driving increased demand for outsourcing lab services to specialized service providers. With many pharmaceutical companies increasingly partnering with CROs for preclinical and clinical trials, there is a need for CROs to invest in advanced technologies to enhance process efficiency.

Regulatory support and Government initiatives: With regulatory agencies across the globe requiring companies to comply with stringent regulations, particularly for IVD devices, labs are responding by investing in high-quality

[36] American Society of Gene and Cell Therapy, Citeline

automated diagnostic systems to meet compliance standards. Government-backed funding initiatives in personalized medicine are also driving the adoption of sequencing solutions and biomarker-based diagnostics.

Adoption of research-based tools in clinical settings: The increasing adoption of research-based tools in the clinical setting is a transformative force that is fundamentally reshaping and driving the growth of the scientific lab solutions market. This trend is moving clinical diagnostics from traditional, often manual, methods toward a new era of precision, automation, and data-driven insights. For instance, NGS, once a tool exclusive to research labs for whole-genome sequencing, is now a cornerstone of clinical diagnostics, particularly in oncology and rare disease genetics. The increased volume of complex tests is driving the demand for specialized reagents, test kits, and consumables required for NGS, PCR, and other molecular diagnostics.

6.3. Competitive Landscape in the Scientific Lab Solutions Market

While global leaders dominate through their established networks and expansive portfolios, emerging players, especially based out of the Asia-Pacific, are creating their own niche with cost-effective and high-throughput solutions.

The scientific lab solutions market is undergoing a significant transformation, driven by technological advancements in proteomics, genomics, and cell-based analysis. On one hand, emerging companies are heading towards cost-effective solutions with a faster turnaround and increased accuracy. But on the other hand, there is a shift toward lab automation and AI-driven analytics fueled by the increasing demand for precision medicine and decentralized diagnostics. In the Asia-Pacific region, there is also a shift in the regulatory landscapes, which is expected to aid the growth of the overall market and also some of the regional players.

Established players such as Thermo Fisher Scientific, Agilent Technologies, and Merck Group, with their vast global network and product portfolio, continue to dominate the laboratory solutions market. Yet, there are several promising players, particularly in the Asia-Pacific, who are rapidly expanding based on the growing demand for services such as biomarker discovery, next-generation sequencing (NGS), high-throughput automation, etc. Integris Medtech is one of the largest scientific lab solutions companies in Southeast Asia.

Table 6.2: Competitive Landscape of select companies in Scientific Lab Solutions

Company	Headquarters	Operational Footprint	Scientific Lab Solutions Product Portfolio
Thermo Fisher Scientific	Waltham, Massachusetts, USA	Global presence, network across the Americas, Europe, and Asia-Pacific	Mass spectrometry, Next-generation sequencing platforms, Gene expression assays, Cell culture solutions, Transfection reagents
Merck Group (MilliporeSigma)	Darmstadt, Germany	Global presence, network across 70+ countries	Mass spectrometry reagents, protein assays, CRISPR tools, DNA/RNA purification, Live-cell imaging, Cell Assays, Chemical reagents
Agilent Technologies	Santa Clara, California, USA	Global presence, network across the Americas, Europe, and Asia-Pacific	Chromatography, protein microarrays, Sequencing solutions, Flow cytometry, Imaging systems, Lab automation
Danaher	Washington, D.C, USA	Global presence in 50 different countries and	Flow cytometry and lab Automation Solutions, Protein consumables, Industrial

		700 locations across the globe	Filtration, Genomics, Molecular diagnostics, Bioprocessing, Biopharma manufacturing
IQVIA	Durham, North Carolina, USA	Global presence, network across the Americas, Europe, and Asia-Pacific	Biomarker discovery services, Spatial genomics, Flow cytometry, Immunoassays
Illumina	San Diego, California, USA	Direct operations spanning Americas, Europe, Asia-Pacific; multiple labs and offices worldwide	NGS and multiomic platforms; advanced biomarker discovery; high-throughput RNA/protein sequencing; end-to-end automation (library prep to analytics); proprietary data analysis software
Qiagen	Hilden, Germany; Venlo, Netherlands	Subsidiaries in 25+ countries; partnerships in 60+ markets; regional HQs in Germany, US, China, Singapore	Integrated sample-to-insight workflows; multimodal sequencing (DNA/RNA); automated biomarker discovery; RNA/DNA quantification; informatics and digital PCR technologies
PerkinElmer	Waltham, Massachusetts, USA	Active in 150+ countries; offices in 35+ nations	Automated NGS library preparation; single-cell, genomic, and exome biomarker platforms; integrated analytics for high-throughput sequencing workflows
Tecan Group	Männedorf, Switzerland	Based out of Europe, strong presence in North America and Asia	Liquid handling for protein studies, Automation for sequencing workflows, Cell imaging systems, Lab automation
BGI Genomics	Shenzhen, China	Based out of China, expanding in APAC, Europe, and North America	Next-generation sequencing services, precision medicine, and Bioinformatics
Shanghai Kehua Bio-engineering (KHB)	Shanghai, China	Dominant presence in China, growing APAC footprint	ELISA kits, protein assays, Diagnostic kits, PCR systems, Clinical diagnostics solutions
Integris Medtech	Delhi NCR, India	India, Europe, Latin America, APAC	Cell biology, Antibodies, Genomics, Proteomics, Chromatography, Consumables

Source: Company website. Note: Operational footprint is not limited to Scientific Lab Solutions.

7. Industry Threats and Challenges for MedTech Companies

The medical device industry, while experiencing continuous innovation and growth, faces a complex array of threats and challenges that demand constant vigilance and strategic adaptation. These issues can impact everything from product development and market entry to patient safety and financial viability. Below are some of the major threats and challenges faced by medical device companies.

Regulatory Complexity: Medical devices are subject to stringent regulations globally, such as the EU MDR (Medical Device Regulation) in Europe and FDA requirements in the US. Medical device companies must navigate a labyrinth of regulations that vary by market and are frequently revised.

Interventional Product Portfolio international standards (such as ISO 13485:2016) and evolving requirements like the EU Medical Device Regulation (MDR) and US FDA Quality System Regulation (QSR) make compliance increasingly challenging. Regulatory uncertainty, especially in major markets like the US and EU, can delay product launches and increase costs.

Quality Management and Product Recalls: Maintaining high product quality is essential, as failures can lead to costly recalls, reputational damage, and even patient harm. Companies spend significant resources on quality management systems (QMS) and post market surveillance to meet regulatory demands and minimize risks. The cost of poor quality and recalls can be devastating, sometimes leading to operational shutdowns or bankruptcy.

Supply Chain Disruptions: The industry continues to grapple with supply chain challenges, including raw material shortages, logistical delays, and geopolitical disruptions. Overreliance on specific suppliers or regions increases vulnerability to shocks. Companies are now diversifying suppliers and production locations to build resilience. Excess or misaligned inventory from risk mitigation efforts can cause financial strain.

Economic Pressures and Pricing: Inflation, rising production costs, and tightening healthcare budgets are squeezing margins for device manufacturers. Companies face constant pressure to differentiate their products, innovate rapidly, and offer competitive pricing. Global competition, especially from companies offering lower-cost solutions, puts additional pressure on pricing and profitability. Mandatory price controls and bulk procurement by large healthcare providers further limit pricing flexibility. Healthcare providers and payers are increasingly scrutinizing costs, leading to demands for value-based care and alternative pricing models (e.g., outcome-based pricing, subscription models) that shift risk onto manufacturers. This forces companies to balance innovation with affordability and demonstrate clear economic value.

Innovation Barriers and High R&D Costs: Developing new medical devices is expensive and risky, with long timelines from concept to market and significant regulatory hurdles. High-profile product failures can lead to legal liabilities and stricter regulations, discouraging innovation. Companies must balance the need for innovation with the risks and costs associated with R&D and market entry.

Counterfeit and Substandard Products: Developing innovative medical devices requires substantial R&D investment, making IP a critical asset. Companies must aggressively protect their patents, trademarks, and trade secrets from infringement and counterfeiting, which can dilute market share, damage reputation, and pose risks to patient safety. The proliferation of counterfeit or substandard devices undermines trust in the industry and exposes legitimate companies to legal and reputational risks. Such products can harm patients and erode confidence in medical technologies.

Geopolitical and Trade Risks: Global economic decoupling, local manufacturing mandates, and regulatory isolationism, particularly between the US and China, pose risks to market access, supply chains, and intellectual property protection. Companies must adapt to shifting trade flows, sanctions, and local content requirements. To avoid impact on geopolitical risks, companies need to actively reconfigure their distribution and manufacturing strategies to enhance resilience and mitigate future disruptions. Some of the strategies adopted to improve resilience and reduce lead times are diversification of sourcing and manufacturing footprint, enhanced supply chain visibility and digital transformation, and inventory management strategies.

8. Competitive Benchmarking of Companies in the Cardiovascular, Clinical Diagnostics, and Scientific Lab Solutions Industry

8.1. Capabilities Analysis of Select Global and Indian Companies in Cardiovascular Devices

Table 8.1: Competitive Landscape: Comparison of Cardiovascular Interventional Product Portfolio of Select global and Indian companies*

Company	Drug Eluting Stent (DES)	Bare metal stents (BMS)	Coronary Drug Coated Balloons (DCB)	PTCA Balloon Catheter	PBMV Balloon Catheter	Intravascular Lithotripsy (IVL)*	Diagnostic Catheter	Other Vascular Accessories
Select global companies								
Abbott	✓	X	X	✓	X	X	✓	✓
Boston Scientific	✓	X	✓	✓	✓	X	✓	✓
Medtronic	✓	X	✓	✓	✓	X	✓	✓
Terumo	✓	X	✓	✓	✓	X	✓	✓
MicroPort	✓	X	✓	✓	X	X	X	✓
Select Indian companies								
Integris Medtech	✓	✓	✓	✓	✓	✓	✓	✓
Micro Life Sciences (Meril Lifesciences)	✓	✓	X	✓	X	X	X	X
Sahajanand Medical Technologies	✓	X	✓	✓	X	X	X	✓
Relisys Medical Devices	✓	✓	X	✓	X	X	✓	✓
Polymed	X	X	X	✓	X	X	✓	✓

Source: Company websites, Frost & Sullivan

** Offering through either branded products or a distribution partnership*

8.2. Capabilities Analysis of Select Global and Indian Companies in Clinical Diagnostics and Scientific Lab Solutions

Table 8.2: Competitive Landscape: Comparison of Clinical Diagnostics and Scientific Lab Solutions Product Portfolio of Select global and Indian companies*

Company	Clinical diagnostics						Scientific lab solutions			
	Immuno-diagnostics	Clinical Chemistry	Hematology	PoCT	Molecular Diagnostics	Electrolyte Analyzer	Cell Biology	Antibodies	Genomics	Proteo-mics
Select global companies										
Abbott	✓	✓	✓	✓	✓	X	X	X	X	X
Roche	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Thermo Fisher Scientific	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
bioMérieux	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Bio-Rad Laboratories	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Becton, Dickinson & Company	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Danaher Corporation (Cytiva)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Select Indian companies										
Integris Medtech	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
TransAsia Biomedical (Erba Diagnostics)	✓	✓	✓	X	✓	X	X	X	X	X
Agappe	✓	✓	✓	✓	✓	✓	X	X	X	X
J Mitra	✓	X	X	X	X	X	X	X	X	X
Molbio Diagnostics	✓	X	X	✓	✓	X	X	X	X	X
Morepen	X	X	X	✓	X	X	X	X	X	X

Source: Company websites, Frost & Sullivan

** Offering through either branded products or a distribution partnership*

Integris Medtech is the only company among the assessed global and Indian peers with a presence across a wide range of cardiovascular interventional products. The company's portfolio is among the most extensive for interventional cardiology procedures. Integris Medtech is the second largest Indian headquartered diversified MedTech platform in terms of operating revenue for Fiscal 2025 and the second largest Indian coronary stent manufacturer by sales volume for Fiscal 2025, holding an estimated 22.0% market share in DES used in percutaneous coronary intervention. Further, the company is one of the largest scientific lab solutions companies in Southeast Asia. Integris MedTech became the global benchmark for expanding Intravascular Lithotripsy (IVL) in emerging markets. In 2024, Integris Medtech launched Protégé Paclitaxel-coated balloon and led the creation of the "Minimal Metal Plasty" (MMP) market. Through direct engagement with 550+ cardiologists in over 250 centers within a year, the company quickly rose to the number 3 position in the Indian DCB market. In Fiscal 2025, the company penetrated the rapidly evolving Intravascular Ultrasound (IVUS) segment, reaching 8.0% market share within a year. Additionally, Integris Medtech has conducted below listed clinical research to evaluate performance outcomes of its cardiovascular devices.

Table 8.3: Clinical Research on Performance Outcomes of Cardiovascular Devices

Study Name	Journal	Centres	Patients	Number of Patients
ISAR-TEST 5	Circulation.2011 Aug 2;124(5):624-32	Germany	Patients older than 18 years of age with ischemic symptoms or evidence of myocardial ischemia in the presence of ≥50% de novo stenosis located in the native coronary vessels	3,002
	Minerva Med. 2023 Oct;114(5):590-600			
	JACC Cardiovasc Interv. 2016 Apr 25;9(8):784-792			
	J Am Coll Cardiol. 2020 Jul 14;76(2):146-158			
ISAR- Test 5 (diabetes mellitus subgroup analysis)	Cardiovasc Diabetol. 2016 Sep 1;15(1):124			870
	Clin Res Cardiol. 2021 Oct;110(10):1586-1598			

Table 8.3: Clinical Research on Performance Outcomes of Cardiovascular Devices				
Study Name	**Journal**	**Centres**	**Patients**	**Number of Patients**
ISAR-TEST 5 (STEMI patient subgroup analysis)	Catheter Cardiovasc Interv. 2017 Feb 15;89(3):367-374			311
ISAR-TEST 4 and ISAR-TEST 5 pooled analysis	Clin Res Cardiol. 2022 Jul;111(7):78	Germany	Patients older than 18 years with ischemic symptoms or evidence of myocardial ischemia in the presence of ≥50% de novo stenosis located in the native coronary vessels	4,953
ISAR-TEST 4	Eur Heart J. 2009 Oct;30(20):2441-9 J. Am. Coll. Cardiol. 2011;58;1325-1331 EuroIntervention. 2016 Mar;11(12):1372-9 Circulation. 2019 Jan 15;139(3):325-333	Germany	Patients older than age 18 with ischaemic symptoms or evidence of myocardial ischaemia (inducible or spontaneous) in the presence of ≥50% de novo stenosis located in native coronary vessels	2,603
ISAR-TEST 4 (diabetes mellitus subgroup analysis)	J Am Heart Assoc. 2021 Jun 15;10(12):e020165			1,951
ISAR-TEST 2	J Am Coll Cardiol. 2010 Jun 8;55(23):2536-43	Germany	Patients undergoing coronary stenting of de novo lesions in native vessels	1,007
ISAR-TEST 3	Heart. 2009 Sep;95(18):1489-94	Germany	Patients with de novo coronary lesions in native vessels	605
Safety and efficacy of the Yukon Choice Flex sirolimus-eluting coronary stent in an all-comers population cohort	Indian Heart J. 2014 May-Jun;66(3):345-9	Germany	Patients presenting with ischemic symptoms or signs of myocardial ischemia in the presence of ≥50% coronary stenosis	778
One-year clinical outcomes of different coronary drug eluting stents—Data from a prospective registry	Indian Heart J. 2018 Jul-Aug;70(4):580-583	India	All subsequent patients who underwent coronary intervention	5436
One-year clinical outcome of percutaneous coronary intervention with very long (40 mm) drug-eluting stent	Indian Heart J. 2018 Dec;70 Suppl 3(Suppl 3):S285-S289	India	Patients who underwent coronary stent implantation with at least one DES of length 40 mm and above	343

Table 8.3: Clinical Research on Performance Outcomes of Cardiovascular Devices				
Study Name	**Journal**	**Centres**	**Patients**	**Number of Patients**
Real-World Clinical Outcomes of Indigenous Biodegradable Polymer Drug-Eluting Stents	Cureus. 2021 Sep 11;13(9):e17886	India	Patients undergoing intracoronary stenting using bioabsorbable or polymer-free drug-eluting stents (DES) from Indian manufacturers	210
Long term safety and efficacy of the Yukon Choice Flex sirolimus eluting coronary stent-a real-world data from India	Indian Heart J. 2021 Nov-Dec;73(6):733-736	India	Patients with ACS or chronic coronary syndrome, who underwent percutaneous coronary intervention (PCI) with YCF stent from November 2015 till February 2017 were enrolled	168
Evaluation of safety and efficacy of sirolimus eluting coronary stent yukon choice flex in all comer coronary artery disease patients a single center experience	S. Kasturi. Sunshine Hospital, Cardiology, Secunderabad, India	India	Patients with CAD who were implanted with Yukon Choice Flex- Sirolimus Eluting Stent (YCF) from January 2015 to March 2017.	1,000
Pioneer registry	Indian Heart J. 2023 Jan-Feb;75(1):25-30	50 sites in India	Patients presenting acute coronary syndrome undergoing PCI and stent deployment	999
GLP 1	J Cardiovasc Transl Res. 2025 Aug 15	Germany	Animal Study	Animal Study
Influence of Stent Surface Topography on the Outcomes of Patients Undergoing Coronary Stenting: A Randomized Double-Blind Controlled Trial	Catheter Cardiovasc Interv. 2005 Jul;65(3):374-80	Germany	Patients with symptomatic coronary artery disease and significant angiographic stenosis in native coronary vessels	200
The pre-clinical assessment of rapamycin-eluting, durable polymer-free stent coating concepts	Biomaterials. 2009 Feb;30(4):632-7	Germany	Animal Study	Animal Study
PEARL registry	J Invasive Cardiol. 2022 Jun;34(6):E462-E468	Netherlands	Included ISR or de novo coronary lesions	513

Table 8.3: Clinical Research on Performance Outcomes of Cardiovascular Devices				
Study Name	**Journal**	**Centres**	**Patients**	**Number of Patients**
	J of Clinical Cardiology & Cardiovascular Interventions 2021		where the use of DCB was considered to be more favourable than stent placement	200

Outlined below are the ongoing clinical studies:

Table 8.4: Ongoing Clinical Research						
Study Name	**Device**	**Country**	**Centres**	**Patients**	**Target Patients**	**Current Status**
Drug-Eluting Stents						
YuChooSeR	Yukon Chrome PC, Yukon Choice PC	France	23	Patients with symptomatic ischemic heart disease requiring stenting, used in routine clinical practice	2,721	Study Completed
e-Yukon	Yukon Chrome PC, Yukon Choice PC, Yukon Choice Flex	UK, Netherlands, KSA, UAE	11	CAD patients	708	Study Ongoing
Transever	ISAR Summit	India	33	CAD patients	1000	Study Ongoing
Secure Global Registry	VIVO ISAR	India + International	43	Patients undergoing percutaneous coronary intervention	2000	Study Ongoing
Celebrity Observatory	VIVO ISAR	France	30	Patients undergoing percutaneous coronary intervention and short dual-antiplatelet therapy in real world population	3000	Study Ongoing

Table 8.4: Ongoing Clinical Research						
Study Name	**Device**	**Country**	**Centres**	**Patients**	**Target Patients**	**Current Status**
Pro-Heal	VIVO ISAR	Spain	4	CAD patients having two angiographically similar lesions	40	Study Ongoing
PMCF	YCPC	India	5	CAD patients	288	Study Ongoing
PMCF	Choice Flex	India	8	CAD patients	288	Study Ongoing
PMCF	Vivo ISAR	India	6	CAD patients	288	Study Ongoing
Protect-I	Protégé	India	30	Patients with symptomatic coronary artery disease (including those with acute coronary syndromes (except Acute STEMI) or Chronic Coronary Syndromes) with either symptoms and/or ischemia.		Study Ongoing
Coated	Protégé	India	1	CAD patients		Study Ongoing
Repeat Registry	Protégé	U.K.	10	CAD patients		Study not yet started
Sparx	Protégé	International	30	Patients with non-ST elevation acute coronary syndrome (NSTEACS) or chronic coronary syndrome (CCS)		Study not yet started
Bliss	Protégé	India	10	Patients with Left Main Bifurcation lesions with metal miss at the CX Ostium.		Study not yet started
Shock India Registry	IVL	India	54	CAD patient with Calcified Coronary Arteries in Real World Indian Population		Study Completed
Optima SC Registry	Optima SC	India	5	Coronary Artery Disease (CAD) patients		Study Completed
Optima NC Registry	Optima NC	India	5	Coronary Artery Disease (CAD) patients		Study Completed

Table 8.4: Ongoing Clinical Research						
Study Name	**Device**	**Country**	**Centres**	**Patients**	**Target Patients**	**Current Status**
Expand ISR	OPN NC	India	1	In-Stent Restenosis		Study not yet started
HaemodynamX	Aortic flow diffuser	India	2	Patients with Severe aortic stenosis		Study Ongoing

8.2.1. Financial Comparison Of Integris Medtech And Select Unlisted Indian MedTech Peers

	Table 8.4A: Financial and Operational KPIs of Integris Medtech and Select Comparable Unlisted Indian MedTech Peers, FY 2025 (All financial figures in INR million except ratios)							
Parameter/ Company	**Integris Medtech (Proforma)**	**Integris Medtech (Audited)**	**Sahajanand Medical Technologies**	**Micro Life Sciences**	**Relisys Medical**	**Trivitron Healthcare**	**Transasia Bio-Medicals**	**Agappe Diagnostics**
Operating Revenue	23,328.12	19,024.66	10,248.79	48,928.00	NA	NA	NA	NA
Gross Profit	10,109.26	8,361.49	7,744.77	35,868.80	NA	NA	NA	NA
Gross Margin	43.34%	43.95%	75.57%	73.31%	NA	NA	NA	NA
EBITDA	3,837.56	3,093.98	1,280.22	12,840.40	NA	NA	NA	NA
EBITDA Margin	16.45%	16.26%	12.49%	26.24%	NA	NA	NA	NA
Adjusted EBITDA	4,064.11	3,320.53	1,317.19	12,840.40	NA	NA	NA	NA
Adjusted EBITDA Margin	17.42%	17.45%	12.85%	26.24%	NA	NA	NA	NA
Restated profit/loss) for the period/year	677.00	706.84	251.52	7,293.60	NA	NA	NA	NA
PAT Margin	2.90%	3.72%	2.45%	14.91%	NA	NA	NA	NA
Adjusted PAT	1,094.85	1,033.46	401.81	7,293.60				
Adjusted PAT Margin	4.69%	5.43%	3.92%	14.91%				
Net Working Capital (in Days)	124	124	152	186	NA	NA	NA	NA
Net Debt /EBITDA	2.72x	3.12x	1.15x	0.86x	NA	NA	NA	NA
RoE	4.45%	5.35%	4.26%	19.29%	NA	NA	NA	NA
Adjusted RoE	7.20%	7.82%	6.80%	19.29%	NA	NA	NA	NA
RoNW	1.48%	1.84%	3.60%	21.05%	NA	NA	NA	NA
RoCE (excluding goodwill and	20.03%	14.51%	9.93%	25.14%	NA	NA	NA	NA

other intangible assets)								

Source: Company financial statements; For privately listed companies, financial benchmarking is based on available information

Table 8.4B: Financial and Operational KPIs of Integris Medtech and Select Comparable Unlisted Indian MedTech Peers, FY 2024 (All financial figures in INR million except ratios)

Parameter/ Company	Integris Medtech	Sahajanand Medical Technologies	Micro Life Sciences	Relisys Medical	Trivitron Healthcare	Transasia Bio-Medicals	Agappe Diagnostics
Operating Revenue	15,533.82	9,016.04	34,956.50	1,643.40	4,522.20	NA	4,425.97
Gross Profit	6,724.95	6,698.18	25,572.00	1,413.99	2,121.88	NA	1,974.52
Gross Margin	43.29%	74.29%	73.15%	86.04%	46.92%	NA	44.61%
EBITDA	1,904.54	1,105.74	6,739.10	541.32	(166.08)	NA	413.30
EBITDA Margin	12.26%	12.26%	19.28%	32.94%	(3.67%)	NA	9.34%
Adjusted EBITDA	1,906.17	1,120.99	6,739.10	541.32	(166.08)	NA	413.30
Adjusted EBITDA Margin	12.27%	12.43%	19.28%	32.94%	(3.67%)	NA	9.34%
Restated profit/loss) for the period/year	(48.84)	(73.54)	3,328.40	363.02	(114.67)	NA	174.92
PAT Margin	(0.31%)	(0.82%)	9.52%	22.09%	(2.54%)	NA	3.95%
Adjusted PAT	214.55	(73.54)	3,328.40	363.02	(114.67)	NA	174.92
Adjusted PAT Margin	1.38%	(0.82%)	9.52%	22.09%	(2.54%)	NA	3.95%
Net Working Capital (in Days)	141	156	173	328	64	NA	127
Net Debt /EBITDA	3.03x	(1.09x)	0.76x	0.05x	(13.97x)	NA	1.14x
RoE	(0.31%)	(1.30%)	10.97%	14.64%	(10.64%)	NA	6.96%
Adjusted RoE	1.36%	(1.30%)	10.97%	14.64%	(10.64%)	NA	6.96%
RoNW	(0.44%)	(2.36%)	12.23%	14.64%	(13.12%)	NA	6.96%
RoCE (excluding goodwill and other intangible assets)	8.33%	7.71%	17.53%	23.36%	(13.13%)	NA	8.60%

Source: Company financial statements; For privately listed companies, financial benchmarking is based on available information

Table 8.4C: Financial and Operational KPIs of Integris Medtech and Select Comparable Unlisted Indian MedTech Peers, FY 2023 (All financial figures in INR million except ratios)

Parameter/ Company	Integris Medtech	Sahajanand Medical Technologies	Micro Life Sciences	Relisys Medical	Trivitron Healthcare	Transasia Bio-Medicals	Agappe Diagnostics

Operating Revenue	13,481.04	7,958.66	23,582.90	1,576.25	4,877.90	14,456.28	3,904.52
Gross Profit	5,725.94	6,017.18	15,341.70	1,323.21	2,117.95	8,651.45	1,804.09
Gross Margin	42.47%	75.61%	65.05%	83.95%	43.42%	59.85%	46.21%
EBITDA	1,688.24	1,160.69	4,560.50	553.39	(211.24)	2,776.94	438.61
EBITDA Margin	12.52%	14.58%	19.34%	35.11%	(4.33%)	19.21%	11.23%
Adjusted EBITDA	1,693.04	1,199.91	4,560.50	553.39	(211.24)	2,776.94	438.61
Adjusted EBITDA Margin	12.56%	15.08%	19.34%	35.11%	(4.33%)	19.21%	11.23%
Restated profit/loss) for the period/year	(405.41)	119.34	5,048.80	361.22	(316.86)	(872.06)	234.65
PAT Margin	(3.01%)	1.50%	21.41%	22.92%	(6.50%)	(6.03%)	6.01%
Adjusted PAT	427.63	119.34	5,156.20	361.22	(316.86)	(3,265.76)	234.65
Adjusted PAT Margin	3.17%	1.50%	21.86%	22.92%	(6.50%)	(22.59%)	6.01%
Net Working Capital (in Days)	129	151	158	268	50	186	149
Net Debt /EBITDA	2.01x	0.76x	1.95x	(0.04x)	(9.31x)	0.24x	0.94x
RoE	(2.77%)	2.08%	23.97%	17.08%	(39.51%)	(6.15%)	9.91%
Adjusted RoE	2.93%	2.08%	24.48%	17.08%	(39.51%)	(23.02%)	9.91%
RoNW	(1.85%)	1.47%	28.07%	17.08%	(46.41%)	(6.15%)	9.91%
RoCE (excluding goodwill and other intangible assets)	9.41%	11.04%	15.02%	27.96%	(16.92%)	17.13%	12.31%

Source: Company financial statements; For privately listed companies, financial benchmarking is based on available information

8.3. Financial and Operational KPIs of Integris Medtech and Select Publicly Listed Indian MedTech Peers

Financial and Operational KPIs of Integris Medtech and Select Listed Indian MedTech Peers, 1Q FY26 (All financial figures in INR million except ratios and EPS)				
Parameter/ Company	Integris Medtech (Proforma)	Integris Medtech (Audited)	Poly Medicure*	Laxmi Dental*
Operating Revenue	6,064.99	4,852.54	4,032.10	655.97
Gross Profit	2,687.25	2,187.84	2,759.80	480.89
Gross Margin	44.31%	45.09%	68.45%	73.31%
EBITDA	1,008.33	787.31	1,074.63	119.08
EBITDA Margin	16.63%	16.22%	26.65%	18.15%
Adjusted EBITDA	1,084.41	863.39	1,074.63	119.08

Adjusted EBITDA Margin	17.88%	17.79%	26.65%	18.15%
Restated profit/ (loss) for the period/year	301.23	2,675.67	930.83	83.30
PAT Margin	4.97%	55.14%	23.09%	12.70%
Adjusted PAT	335.28	313.49	930.83	83.30
Adjusted PAT Margin	5.53%	6.46%	23.09%	12.70%
Net Working Capital (in Days)	NA	152	NA	NA
Net Debt /EBITDA	NA	3.33x	NA	NA
RoE	NA	11.15%	NA	NA
Adjusted RoE	NA	1.31%	NA	NA
RoNW	NA	6.76%%	NA	NA
RoCE (excluding goodwill and other intangible assets)	NA	4.23%	NA	NA
Face Value per Equity Share (INR)	1.00	1.00	5.00	2.0
EPS Basic (INR)	2.51	28.00	9.19	1.53
EPS Diluted (INR)	2.48	27.61	9.17	1.52
Net Asset Value per Equity Share	NA	414.12	NA	NA
Operational Key Performance Indicators				
Number of Sales Team members	592	367	NA	NA
Revenue Split by product categories: Lab Solutions (Scientific Lab Solutions and Clinical Diagnostics):				
Scientific Lab Solutions	1,477.19	1,354.17	NA	NA
Clinical Diagnostics	2,949.56	1,873.28	NA	NA
Cardiovascular: **DES and Balloon**	957.70	957.70		
Other cardiovascular products	680.54	667.39	NA	NA
Revenue Split by geography:				
India	1,656.98	1,643.83	NA	NA
Europe	477.36	477.36	NA	NA
Asia (Ex-India)	3,777.29	2,578.00	NA	NA
RoW	153.36	153.35	NA	NA
Manufacturing capacity and utilization	91.16%	91.16%	NA	NA

*Source: Company financial statements. *Data based on unaudited published quarterly results; values based on available information.*

Financial and Operational KPIs of Integris Medtech and Select Listed Indian MedTech Peers, FY25 (All financial figures in INR million except ratios and EPS)				
Parameter/ Company	**Integris Medtech (Proforma)**	**Integris Medtech (Audited)**	**Poly Medicure**	**Laxmi Dental**
Operating Revenue	23,328.12	19,024.66	16,698.32	2,391.07
Gross Profit	10,109.26	8,361.49	11,151.42	1,818.66
Gross Margin	43.34%	43.95%	66.78%	76.06%
EBITDA	3,837.56	3,093.98	4,796.51	434.44
EBITDA Margin	16.45%	16.26%	28.72%	18.17%
Adjusted EBITDA	4,064.11	3,320.53	4,808.75	456.34
Adjusted EBITDA Margin	17.42%	17.45%	28.80%	19.09%
Restated profit/loss) for the period/year	677.00	706.84	3,385.57	318.34
PAT Margin	2.90%	3.72%	20.27%	13.31%
Adjusted PAT	1,094.85	1,033.46	3,385.57	388.61
Adjusted PAT Margin	4.69%	5.43%	20.27%	16.25%
Net Working Capital (in Days)	124	124	120	36
Net Debt /EBITDA	2.72x	3.12x	(2.14x)	(2.07x)
RoE	4.45%	5.35%	12.24%	15.25%
Adjusted RoE	7.20%	7.82%	12.24%	18.62%
RoNW	1.48%	1.84%	12.26%	16.09%
RoCE (excluding goodwill and other intangible assets)	20.03%	14.51%	23.59%	24.29%
Face Value per Equity Share (INR)	1.00	1.00	5.00	2.00
EPS Basic (INR)	5.00	5.82	34.13	6.07
EPS Diluted (INR)	4.93	5.73	34.11	6.05
Net Asset Value per Equity Share	338.66	316.09	278.46	37.71
	Operational Key Performance Indicators			
Number of Sales Team members	453	363	NA	NA
Revenue Split by product categories:				
Lab Solutions (Scientific Lab Solutions and Clinical Diagnostics):				
Scientific Lab Solutions	6,098.81	5,601.18	NA	NA
Clinical Diagnostics	10,530.52	6,811.30	NA	NA
Cardiovascular:				
DES and Balloon	3,436.45	3,436.45	NA	NA
Other cardiovascular products	3,262.34	3,175.73	NA	NA

Revenue Split by geography:				
India	6,761.48	6,674.88	4,841.29	1,577.79
Europe	1,514.22	1,514.22	NA	NA
Asia (Ex-India)	14,323.75	10,106.89	NA	NA
RoW	728.67	728.67		
Manufacturing capacity and utilization	86.39%	86.39%	NA	NA

Source: Company financial statements. For Laxmi Dental, restated consolidated financials have been considered for computation for FY24 and FY23.

Financial and Operational KPIs of Integris Medtech and Select Listed Indian MedTech Peers, FY24 (All financial figures in INR million except ratios and EPS)			
Parameter/ Company	**Integris Medtech**	**Poly Medicure**	**Laxmi Dental**
Financial Key Performance Indicators			
Operating Revenue	15,533.82	13,757.96	1,935.55
Gross Profit	6,724.95	8,931.87	1,450.66
Gross Margin	43.29%	64.92%	74.95%
EBITDA	1,904.54	3,759.16	243.61
EBITDA Margin	12.26%	27.32%	12.59%
Adjusted EBITDA	1,906.17	3,780.31	243.61
Adjusted EBITDA Margin	12.27%	27.48%	12.59%
Restated profit/loss) for the period/year	(48.84)	2,582.60	252.29
PAT Margin	(0.31%)	18.77%	13.03%
Adjusted PAT	214.55	2,582.60	251.44
Adjusted PAT Margin	1.38%	18.77%	12.99%
Net Working Capital (in Days)	141	105	64
Net Debt /EBITDA	3.03x	(0.30x)	2.00x
RoE	(0.31%)	17.57%	56.60%
Adjusted RoE	1.36%	17.57%	56.41%
RoNW	(0.44%)	17.60%	58.14%
RoCE (excluding goodwill and other intangible assets)	8.33%	23.96%	13.54%
Face Value per Equity Share (INR)	1.00	5.00	2.00
EPS Basic (INR)	(1.38)	26.92	4.80
EPS Diluted (INR)	(1.38)	26.90	4.80
Net Asset Value per Equity share	313.11	152.90	8.25
Operational Key Performance Indicators			
Number of Sales Team members	367	NA	NA
Revenue Split by product categories: Lab Solutions (Scientific Lab Solutions and Clinical Diagnostics):			
Scientific Lab Solutions	5,260.51	NA	NA

Clinical Diagnostics	4,651.03	NA	NA
Cardiovascular: **DES and Balloon**	3,281.08	NA	NA
Other cardiovascular products	2,341.20	NA	NA
Revenue Split by geography:			
India	6,150.85	4,077.16	1,291.58
Europe	1,038.14	NA	NA
Asia (Ex-India)	7,795.79	NA	NA
RoW	549.04	NA	NA
Manufacturing capacity and utilization	88.99%	NA	NA

Source: Company financial statements. For Laxmi Dental, restated consolidated financials have been considered for computation for FY24 and FY23.

Comparison of Integris MedTech key performance indicators with listed industry peers, FY23 (All financial figures in INR million except ratios and EPS)			
Parameter/ Company	**Integris Medtech**	**Poly Medicure**	**Laxmi Dental**
Financial Key Performance Indicators			
Operating Revenue	13,481.04	11,152.30	1,616.31
Gross Profit	5,725.94	7,093.54	1,198.34
Gross Margin	42.47%	63.61%	74.14%
EBITDA	1,688.24	2,742.78	102.54
EBITDA Margin	12.52%	24.59%	6.34%
Adjusted EBITDA	1,693.04	2,762.05	102.54
Adjusted EBITDA Margin	12.56%	24.77%	6.34%
Restated profit/loss) for the period/year	(405.41)	1,792.83	(41.63)
PAT Margin	(3.01%)	16.08%	(2.58%)
Adjusted PAT	427.63	1,792.83	(45.13)
Adjusted PAT Margin	3.17%	16.08%	(2.79%)
Net Working Capital (in Days)	129	115	50
Net Debt /EBITDA	2.01x	(0.56x)	3.62x
RoE	(2.77%)	14.44%	(21.37%)
Adjusted RoE	2.93%	14.44%	(23.16%)
RoNW	(1.85%)	14.48%	(22.36%)
RoCE (excluding goodwill and other intangible assets)	9.41%	21.58%	(1.33%)
Face Value per Equity Share (INR)	1.00	5.00	2.00
EPS Basic (INR)	(5.99)	18.69	(0.77)
EPS Diluted (INR)	(5.99)	18.67	(0.77)
Net Asset Value per Equity share	323.91	129.13	3.44
Operational Key Performance Indicators			
Number of Sales Team members	351	NA	NA

Revenue Split by product categories:			
Lab Solutions (Scientific Lab Solutions and Clinical Diagnostics):			
Scientific Lab Solutions	4,937.98	NA	NA
Clinical Diagnostics	3,847.55	NA	NA
Cardiovascular:			
DES and Balloon	3,078.93	NA	NA
Other cardiovascular products	1,616.58	NA	NA
Revenue Split by geography:			
India	5,542.89	3,440.05	1,088.20
Europe	297.19	NA	NA
Asia (Ex-India)	6,992.38	NA	NA
RoW	648.58		
Manufacturing capacity and utilization	92.94%	NA	NA

Source: Company financial statements. For Laxmi Dental, restated consolidated financials have been considered for computation for FY24 and FY23.

Formulas used for financial analysis:

- Gross Profit = Operating Revenue less Cost of Materials Consumed less Purchases of Stock-in-Trade less Changes in Inventories
- Gross Margin (%) = Gross Profit divided by Operating Revenue
- EBITDA = Profit Before Exceptional Items and Tax plus Finance Costs plus Depreciation and Amortization Expense less (Other Income less Forex Exchange Gain)
- EBITDA Margin (%) = EBITDA divided by Operating Revenue
- Adjusted EBITDA = EBITDA plus Share-based Payment
- Adjusted EBITDA Margin (%) = Adjusted EBITDA divided by Operating Revenue
- PAT Margin (%) = Profit for the Year divided by Operating Revenue
- Adjusted PAT = Profit for the Year plus Exceptional Items
- Adjusted PAT Margin (%) = Adjusted PAT divided by Operating Revenue
- Net Debt / EBITDA = (Non-Current Borrowings plus Non-Current Lease Liabilities plus Current Borrowings plus Current Lease Liabilities less Investments less Cash and Cash Equivalents less Bank Balances Other than Cash and Cash Equivalents) divided by EBITDA
- Return on Equity (RoE) (%) = Profit for the Year divided by Total Equity
- Adjusted RoE (%) = Adjusted PAT divided by Total Equity
- Return on Net Worth (RoNW) = Profit for the Year Attributable to Owners divided by Equity Attributable to Owners
- RoCE = (Profit Before Exceptional Items and Tax plus Finance Costs less (Other Income less Forex Exchange Gain)) divided by (Total Equity plus Non-Current Borrowings plus Non-Current Lease Liabilities plus Current Borrowings plus Current Lease Liabilities less Investments less Cash and Cash Equivalents less Bank Balances Other than Cash and Cash Equivalents less Goodwill less Other Intangible Assets less Intangible Assets under Development)