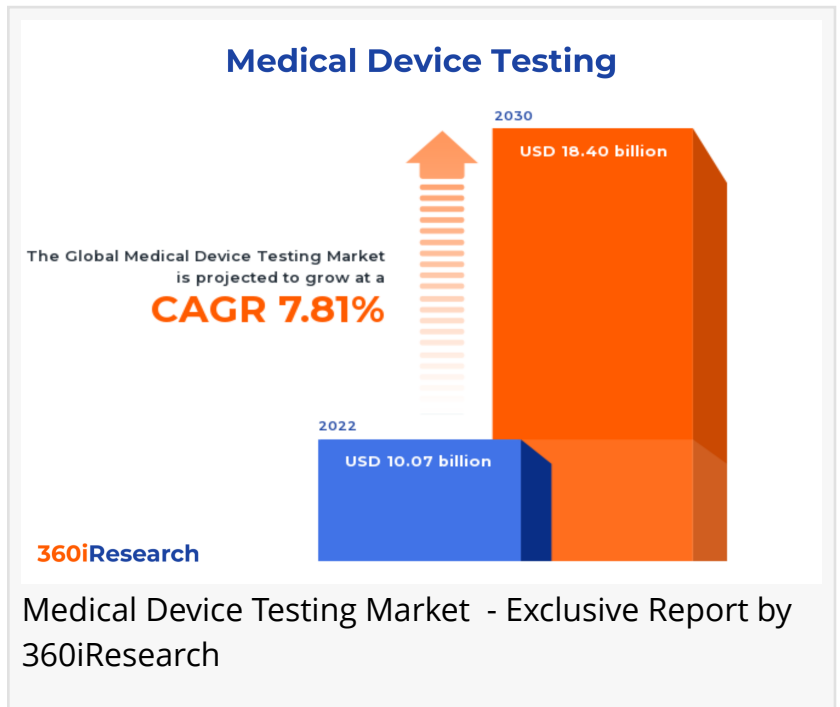


Medical Device Testing Market worth \$18.40 billion by 2030 - Exclusive Report by 360iResearch

The Global Medical Device Testing Market to grow from USD 10.07 billion in 2022 to USD 18.40 billion by 2030, at a CAGR of 7.81%.

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EINPresswire.com/ -- The "[Medical Device Testing Market](#) by Service Type (Certification Services, Inspection Services, Testing Services), Test Type (Chemical, Physical, & Biocompatibility Testing, Cybersecurity Testing, Electrical Safety), Device Class, Phase, Device Type, Sourcing Type, End-Users - Global Forecast 2023-2030" report has been added to 360iResearch.com's offering.



The Global Medical Device Testing Market to grow from USD 10.07 billion in 2022 to USD 18.40 billion by 2030, at a CAGR of 7.81%.

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Medical device testing is the systematic, regulated process of assessing and validating medical devices' safety, reliability, and performance. This extensive process ensures that the device performs as intended and safeguards users, including healthcare professionals and patients, from potential device-related harm. This process often involves a series of rigorous tests adhering to international and national standards and regulations, including those established by organizations such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Innovations in medical device technologies, stringent regulatory compliances, and increasing awareness about patient safety primarily shape market growth. However, the medical

device testing market faces challenges owing to high testing costs acting as a significant barrier for new entrants, and the lengthy approval process for new medical devices may hinder market growth. In addition, the increasing adoption of wearable medical devices, growth in home and remote patient care, and the rising application of AI, IoT, and other innovative technologies in the medical field offer tremendous opportunities for the medical device testing market.

Sourcing Type: Higher preferences for in-house testing for highly proprietary or sensitive devices

In-house testing is conducted within the medical device company's facilities using their employees and resources, which allows for tight control and oversight over the testing process but requires significant investments in infrastructure and personnel. Outsourced testing leverages third-party contract research organizations (CROs) and test labs specializing in medical device testing. Outsourcing reduces the burden on a company's resources but can be costlier and risk exposing intellectual property or trade secrets.

Device Class: Requirement of rigorous PMA processes for class III devices to ensure safety and effectiveness before reaching the market

Class I medical devices are low-risk devices and are subject to the least regulatory control. These include tongue depressors, bedpans, and elastic bandages, among others. Class II medical devices pose a moderate risk and are subject to special controls to ensure safety and effectiveness. Devices, including powered wheelchairs, infusion pumps, and surgical drapes, fall under this category. Manufacturers must clear a 510(k) process to demonstrate substantial equivalence to a predicate device. Class III medical devices support life or pose a serious risk and are subject to the highest level of regulation. These include devices such as pacemakers, heart valves, and orthopedic implants. Manufacturers must undergo a laborious premarket approval application process to establish safety and effectiveness.

End-Users: Proliferating need from medical device manufacturers

Contract manufacturing organizations (CMOs) are critical in medical device testing as they provide various services, including device design and development, manufacturing, packaging, sterilization, and testing. In addition, CMO offers specialized medical device testing services, such as biocompatibility testing, performance testing, and packaging validation. CMOs prioritize accuracy, speed, and compliance with regulatory standards. Manufacturers primarily focus on the production of medical devices and rely heavily on testing services to ensure medical devices are safe, effective, and comply with regulatory standards. Manufacturers significantly prefer testing services that offer a quick turnaround time and cost-effectiveness. Research institutions favor testing services that offer detailed analyses and precise results, as these are essential in verifying and validating their research findings. Research institutions emphasize medical device testing services that provide comprehensive test results and analytical interpretations.

Technology: Escalating adoption of medical device testing services for mobile devices

Active implantable medical devices (AIMDs) are characterized by devices that remain active inside the human body. Such devices include defibrillators, cochlear implants, and neuro-

stimulators. Extensive testing is needed to ensure safety, focusing on battery functionality, biocompatibility, and telemetry. Active medical devices (AMDs), such as pacemakers, infusion pumps, and monitors, require a power source for operation. AMD testing ensures rigorous regulatory requirements, focusing on aspects including electromagnetic compatibility, electrical safety, and software reliability. In-vitro diagnostic medical devices (IVDs) are used for testing samples outside the human body, particularly in a laboratory setting, such as blood glucose tests or pregnancy tests, and ensuring their accuracy, reproducibility & sensitivity is required for IVD testing. Mobile devices in healthcare include smartphones & tablets equipped with medical apps or wearable health monitors. Application functionality, data privacy, and battery life are critical testing areas to ensure such devices' safe and effective use. Non-active medical devices consist of tools that do not require power for operation, such as scalpels, sutures, or hospital beds. Testing for these devices focuses on mechanical safety, materials testing, and sterilization. Ophthalmic medical devices used in eye-related ailments include contact lenses, cataract implants, and laser vision correction equipment. Testing ensures precise optical and mechanical performance and maintains unique biocompatibility requirements. Orthopedic and dental medical devices encompass a wide range, such as artificial joints, dental implants, and braces. Functionality, durability, and biocompatibility testing are essential in these devices, given their long-term use inside the human body. Vascular medical devices treat conditions within blood vessels, such as stents, catheters, and vascular grafts. Critical testing areas are device performance under dynamic vascular conditions, the robustness of the device, and biocompatibility.

Test Type: Emerging applications of cybersecurity testing with advent of advanced technologies in medical devices

Chemical testing checks for harmful chemicals, physical testing examines attributes including durability, and biocompatibility testing confirms devices won't adversely interact with human tissues or fluids. Cybersecurity testing is critical, owing to the increasing digital connectivity of medical devices, which checks for vulnerabilities that could allow unauthorized access or hacking. Electrical safety testing confirms medical devices meet standards for electric shock prevention, electromagnetic compatibility, and other metrics. Environmental testing evaluates medical devices' functions under extreme temperatures, humidity, vibration, or drop impact. Mechanical testing assesses medical device attributes such as tensile strength, hardness, and fatigue resistance.

Phase: Significant penetration of medical devices testing in the clinical phase

A detailed evaluation of the safety and effectiveness of a medical device on human subjects characterizes the clinical phase. Clinical trials are primarily driven by healthcare regulations and the need to ensure patient safety while establishing a device's efficacy. Preceding the clinical phase, the preclinical phase is conducted in laboratories using in-vitro techniques and animal models. The goal is to assess the device's safety profile, biocompatibility, and functional attributes under controlled conditions. This phase is paramount to researchers and physicians for understanding devices' potential benefits and limitations before they reach patients. Preclinical trials are preferred when there's a need for initial safety checks, identifying major

risks, feasibility, and efficacy analysis before exposing a device to humans. Clinical trials are performed to validate the findings in real-world settings and comply with regulatory needs.

Service Type: Growing requirement for inspection services driven by the ever-growing complexity and diversity of medical technologies

Certification services are vital to validate the reliability and viability of medical devices. For manufacturers requiring certification for their medical devices, such services are particularly beneficial for gaining international acceptance and ensuring patient safety. Inspection services guarantee medical devices' physical and functional integrity throughout their lifecycle. Inspection services are the preferred choice for manufacturers to ensure their devices work correctly with minimal potential for faults or malfunctions. Testing services play a pivotal role in assessing medical device performance, safety, and compliance with industry standards. This service type is crucial for manufacturers eager to ensure their products' efficacy and safety before entering the market.

Regional Insights:

In the Americas, the medical device testing market has exhibited resilience and growth in recent years, attributed to the region's stringent regulatory standards promulgated by the Food and Drug Administration (FDA) and the increasing need for high-quality medical devices. The healthcare sector has been poised for innovation fueled by critical factors such as the increasing aging population and the prevailing chronic diseases, including diabetes and cardiovascular disorders. The EMEA region presents an encouraging growth for the medical device testing market. The European market, driven by technological advancements, increased research funding, and high healthcare expenditure, has contributed heavily to medical device testing in the EMEA region. The Middle East and African regions have comparatively less market share but provide substantial growth potential owing to rapidly developing healthcare infrastructure and increasing healthcare spending. Meanwhile, the APAC region encapsulates a vast diversity from mature markets, including Japan and Australia, to emerging ones, such as China and India. The increasing healthcare spending, aging population, and surge in health consciousness in the region fuel this growth. In addition, government policies' encouragement of local manufacturing is potentially stimulating market growth.

FPNV Positioning Matrix:

The FPNV Positioning Matrix is essential for assessing the Medical Device Testing Market. It provides a comprehensive evaluation of vendors by examining key metrics within Business Strategy and Product Satisfaction, allowing users to make informed decisions based on their specific needs. This advanced analysis then organizes these vendors into four distinct quadrants, which represent varying levels of success: Forefront (F), Pathfinder (P), Niche (N), or Vital(V).

Market Share Analysis:

The Market Share Analysis offers an insightful look at the current state of vendors in the Medical

Device Testing Market. By comparing vendor contributions to overall revenue, customer base, and other key metrics, we can give companies a greater understanding of their performance and what they are up against when competing for market share. The analysis also sheds light on just how competitive any given sector is about accumulation, fragmentation dominance, and amalgamation traits over the base year period studied.

Key Company Profiles:

The report delves into recent significant developments in the Medical Device Testing Market, highlighting leading vendors and their innovative profiles. These include 5D Health Protection Group Ltd., Alliance Technologies, LLC, Almac Group Limited, AMETEK, Inc., Applied Technical Services, LLC, Bioneds India Pvt. Ltd., Boston Analytical, Bureau Veritas S.A., Cetecom Advanced GmbH, Charles River Laboratories, Inc., Clark Testing, DDL, Inc., DEKRA SE, Device Conformity and Testing, LLC, Element Materials Technology, Eurofins Scientific SE, ImpactQA, Innovatech Labs, LLC, Intertek Group PLC, iuvo BioScience, LLC, Laboratory Corporation of America Holdings, Maven Profcon Services LLP, Measur Oy, MED Institute Inc., Medical Engineering Technologies, Nemko Group, North American Science Associates, LLC, Pace Analytical Services, LLC, Q Laboratories, Inc., Qualitest Group, Qualizeal India LLP, Sanbor Medical Corporation, ScienceSoft Corporation, SGS S.A., STEMart, Sterigenics U.S., LLC by Sotera Health company, STERIS PLC, TA Instruments by Waters Corporation, Tentamus Group GmbH, Test Labs Ltd., The British Standards Institution, The Smithers Group Inc., TÜV SÜD AG, UL LLC, and WESTPAK, Inc..

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Market Segmentation & Coverage:

This research report categorizes the Medical Device Testing Market in order to forecast the revenues and analyze trends in each of following sub-markets:

Based on Service Type, market is studied across Certification Services, Inspection Services, and Testing Services. The Testing Services commanded largest market share of 47.97% in 2022, followed by Certification Services.

Based on Test Type, market is studied across Chemical, Physical, & Biocompatibility Testing, Cybersecurity Testing, Electrical Safety, Environmental Testing, and Mechanical Testing. The Chemical, Physical, & Biocompatibility Testing commanded largest market share of 31.74% in 2022, followed by Electrical Safety.

Based on Device Class, market is studied across Class I, Class II, and Class III. The Class III commanded largest market share of 58.51% in 2022, followed by Class I.

Based on Phase, market is studied across Clinical and Preclinical. The Clinical commanded

largest market share of 57.46% in 2022, followed by Preclinical.

Based on Device Type, market is studied across Active Implant Medical Device, Active Medical Device, In-Vitro Diagnostic Medical Device, Mobile Medical Devices, Non-Active Medical Device, Ophthalmic Medical Device, Orthopedic & Dental Medical Device, and Vascular Medical Device. The Ophthalmic Medical Device commanded largest market share of 18.84% in 2022, followed by Non-Active Medical Device.

Based on Sourcing Type, market is studied across In-House and Outsourced. The Outsourced commanded largest market share of 52.34% in 2022, followed by In-House.

Based on End-Users, market is studied across Contract Manufacturing Organization, Medical Device Manufacturers, and Research Institutions. The Medical Device Manufacturers commanded largest market share of 46.34% in 2022, followed by Contract Manufacturing Organization.

Based on Region, market is studied across Americas, Asia-Pacific, and Europe, Middle East & Africa. The Americas is further studied across Argentina, Brazil, Canada, Mexico, and United States. The United States is further studied across California, Florida, Illinois, New York, Ohio, Pennsylvania, and Texas. The Asia-Pacific is further studied across Australia, China, India, Indonesia, Japan, Malaysia, Philippines, Singapore, South Korea, Taiwan, Thailand, and Vietnam. The Europe, Middle East & Africa is further studied across Denmark, Egypt, Finland, France, Germany, Israel, Italy, Netherlands, Nigeria, Norway, Poland, Qatar, Russia, Saudi Arabia, South Africa, Spain, Sweden, Switzerland, Turkey, United Arab Emirates, and United Kingdom. The Americas commanded largest market share of 40.43% in 2022, followed by Europe, Middle East & Africa.

Key Topics Covered:

1. Preface
2. Research Methodology
3. Executive Summary
4. Market Overview
5. Market Insights
6. Medical Device Testing Market, by Service Type
7. Medical Device Testing Market, by Test Type
8. Medical Device Testing Market, by Device Class
9. Medical Device Testing Market, by Phase
10. Medical Device Testing Market, by Device Type
11. Medical Device Testing Market, by Sourcing Type
12. Medical Device Testing Market, by End-Users
13. Americas Medical Device Testing Market
14. Asia-Pacific Medical Device Testing Market

15. Europe, Middle East & Africa Medical Device Testing Market
16. Competitive Landscape
17. Competitive Portfolio
18. Appendix

The report provides insights on the following pointers:

1. Market Penetration: Provides comprehensive information on the market offered by the key players
2. Market Development: Provides in-depth information about lucrative emerging markets and analyzes penetration across mature segments of the markets
3. Market Diversification: Provides detailed information about new product launches, untapped geographies, recent developments, and investments
4. Competitive Assessment & Intelligence: Provides an exhaustive assessment of market shares, strategies, products, certification, regulatory approvals, patent landscape, and manufacturing capabilities of the leading players
5. Product Development & Innovation: Provides intelligent insights on future technologies, R&D activities, and breakthrough product developments

The report answers questions such as:

1. What is the market size and forecast of the Medical Device Testing Market?
2. Which are the products/segments/applications/areas to invest in over the forecast period in the Medical Device Testing Market?
3. What is the competitive strategic window for opportunities in the Medical Device Testing Market?
4. What are the technology trends and regulatory frameworks in the Medical Device Testing Market?
5. What is the market share of the leading vendors in the Medical Device Testing Market?
6. What modes and strategic moves are considered suitable for entering the Medical Device Testing Market?

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