

Medical Device Testing and Certification Market Expected to Hit USD 10.2 Billion by 2035 with a Remarkable 6.37% CAGR

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/EINPresswire.com/ -- Medical Device Testing and Certification Market Expands with Surge in Regulatory Demand and Innovation

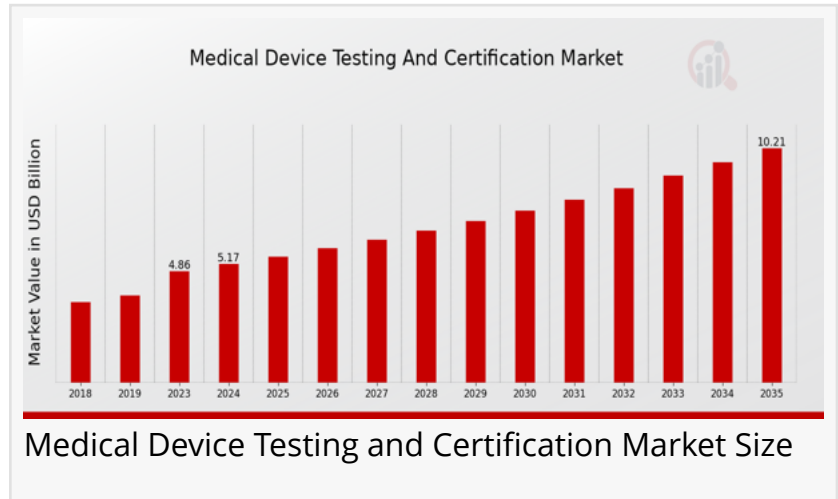
The Medical Device Testing and Certification Market was valued at USD

4.86 billion in 2023, reflecting growing regulatory emphasis on safety, quality, and performance across global healthcare systems. According to MRFR analysis, the market is set to climb to USD 5.17 billion in 2024, with projections reaching approximately USD 10.2 billion by 2035. This expansion corresponds to a compound annual growth rate (CAGR) of 6.37% from 2025 to 2035. Factors driving this growth include increasingly stringent compliance standards, the rapid pace of medical device innovation, and rising international demand for third-party certification to ensure global market access.

Market Scope and Industry Size

As healthcare devices become increasingly digital, portable, and connected, ensuring their safety, accuracy, and compliance has become a top priority. The growing industry size is fueled by strong demand across developed and emerging markets alike. With rising regulatory scrutiny and the globalization of healthcare production and distribution, device testing and certification services are now an indispensable part of the medical device lifecycle.

The market's scope includes all forms of regulatory, quality, and performance testing for active, non-active, implantable, and in vitro diagnostic (IVD) devices. Additionally, regulatory bodies across North America, Europe, and Asia-Pacific are mandating strict pre- and post-market evaluations, further accelerating service demand.



Segment Growth and Market Share

The market is segmented by service type into testing services and certification services. Testing services account for the largest market share, owing to their critical role in safety, electrical, mechanical, and biological compatibility assessments. This segment continues to grow as medical device designs become more intricate and software-driven.

Certification services—including CE marking, ISO 13485 certification, and FDA approvals—are also witnessing strong segment growth, especially as manufacturers seek global market access. Increasing exports and regional harmonization efforts are prompting companies to invest more in high-quality certification to reduce time to market.

By sourcing, the outsourced segment holds a dominant position. Manufacturers are increasingly relying on third-party laboratories and certification bodies to streamline processes, access specialized expertise, and meet fast-evolving international standards efficiently.

In terms of device type, active implantable devices and IVD medical devices are at the forefront. Both categories require intensive testing due to their high risk and regulatory classification, thus representing a significant portion of global testing demand.

Top Companies Driving the Market

Several top companies lead the global medical device testing and certification space, including:

Deloitte
Intertek
BSI Group
Bureau Veritas
DEKRA
UL
SGS
Eurofins Scientific
NSF International
Applus+

These firms offer full-spectrum testing and certification services and have continued to expand their capabilities through digital transformation, laboratory network expansion, and strategic partnerships. Their ability to offer region-specific as well as global compliance solutions gives them a competitive edge.

Emerging Trends and Innovation

One of the most significant emerging trends is the integration of digital technologies such as AI,

machine learning, and IoT simulations into testing environments. These technologies are enabling faster and more reliable testing outcomes, particularly for software-based and connected medical devices.

In addition, remote auditing and virtual inspections have become standard practice in post-pandemic workflows. These innovations support global supply chain continuity while enabling regulatory compliance even under mobility restrictions.

Opportunities in the Global Market

Emerging markets, particularly in the Asia-Pacific region, are providing ample opportunities due to rising healthcare investments, manufacturing expansion, and favorable regulatory reforms. Countries such as India, China, and South Korea are witnessing an influx of medical device exports and startups, intensifying the need for third-party testing partners.

The increasing focus on home healthcare, wearable medical devices, and personalized diagnostics is also creating new demand for specialized testing protocols, opening growth opportunities for niche testing services and software verification labs.

Recent Developments and Strategic Moves

The market has seen several recent developments, including expansions of digital testing infrastructure and collaborations between certification agencies and national regulatory authorities. Firms like TÜV SÜD and Eurofins have broadened their lab capabilities to support faster testing for connected devices and cybersecurity evaluations.

Additionally, many companies are embracing AI-driven quality assurance tools, allowing them to optimize test cycles and deliver results with higher accuracy and shorter turnaround times. These developments are improving operational efficiency while helping clients meet international regulatory deadlines.

Future Outlook for Stakeholders

Looking ahead, the future outlook for the medical device testing and certification market is highly positive. As the medical device industry continues to innovate—especially in AI-enabled, wearable, and implantable technologies—the need for robust, third-party validation will only intensify.

Healthcare systems, regulatory bodies, and medical technology developers must align strategically to meet the dual goals of patient safety and market competitiveness. The evolution of cybersecurity, interoperability standards, and software-as-a-medical-device (SaMD) requirements will drive further market expansion.

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