Analysis of the global Medical Device market

July 2021
Global medical device market is expected to grow to ~$797 bn by 2025

Global Medical Device Market Size ($ bn)

<table>
<thead>
<tr>
<th>Year</th>
<th>Market Size ($ bn)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020</td>
<td>$605.7</td>
</tr>
<tr>
<td>2025</td>
<td>$796.9</td>
</tr>
</tbody>
</table>

Key insights

- Significant growth opportunities in emerging geographies, stagnating growth in established markets
- Convergence of technologies – IoMT, AI/ML, wearable technology, 3D printing, Blockchain, enhanced cybersecurity, and others
- Growing complex regulatory environment; increasing cost pressure from payers & providers

Drivers of Growth

- Rapid integration of advanced technologies
- Shift in consumer demand
- Growing burden of chronic diseases
- Increasing healthcare spending
- Diversified funding support base
- Emerging global markets

Sources: bccresearch.com, grandviewresearch.com
In-vitro diagnostics emerged as the largest segment in the year 2020

In-vitro diagnostics was the largest segment in 2020 with a share of 13.8% of the global market.

In-vitro diagnostics market was valued at $83.4 billion in 2020, and is expected to grow at a CAGR of 4.5% (2021-2027).

Increasing number of testing due to pandemic, growing number of new product launches, and development of automated IVD systems fuel its market growth.

Sources: evidera.com, gradviewresearch.com
COVID-19 impact on US MedTech during H1 2020

Aggregate revenue decline is 5%

2/3 of medtechs report revenue drop in H1 2020

7 of the top 10 companies by revenues report H1 2020 downturns vs. H1 2019

8 companies, primarily focused on elective procedures, saw revenues fall by 15%, but diagnostic companies surged, accounting for

4 of the 6 biggest revenue increases

Sources: jdsupra.com, siteselection.com

MedTech’s role in the COVID-19 response

448
COVID-19 related diagnostics launched in market or in development (as of Aug. 2020)

232
Viral in-vitro diagnostics

148
Antibody in-vitro diagnostics

56
Medical device partnerships (digital, diagnostic testing, scaling manufacturing, telemedicine and virtual care)
Key industry challenges
The challenges impeding the growth of the Medical Device market

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Growing Pricing Pressure</td>
<td>1</td>
<td>Pressure to reduce medical device prices is a key concern for the industry</td>
</tr>
<tr>
<td>Changing consumer demands</td>
<td>2</td>
<td>Medtech consumer requirements are continuously changing; driving the need for innovation</td>
</tr>
<tr>
<td>Non-traditional entrants</td>
<td>3</td>
<td>Growing interest of technology giants in medical devices may hamper the market share of existing players</td>
</tr>
<tr>
<td>Increasing no. of start-ups</td>
<td>4</td>
<td>Increasing number of start-ups are imposing continuous innovation pressure on MedTech companies</td>
</tr>
<tr>
<td>Less regulated geographies</td>
<td>5</td>
<td>Less complex regulations are supporting growth of local innovators; evolving as a competitor for larger players</td>
</tr>
<tr>
<td>Need for evidence</td>
<td>6</td>
<td>Regulatory bodies and providers are demanding “evidence” to ensure safety and effectiveness of devices</td>
</tr>
<tr>
<td>Cybersecurity risks</td>
<td>7</td>
<td>Cybersecurity risk is a major concern for the industry</td>
</tr>
</tbody>
</table>
1. Pricing pressure on medical device manufacturers continues to increase

<table>
<thead>
<tr>
<th>Uncertain regulatory scenario</th>
<th>Increasing negotiating power</th>
<th>Shift to Value Based Care</th>
<th>Reimbursement pressure</th>
<th>Low visibility to OEMs</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Continuously changing on medical devices resulted into relentless downward pressure on pricing</td>
<td>• In the US, group purchasing organizations (GPOs) are consolidating their power</td>
<td>• Shift in focus from devices to more outcome or value-based measures</td>
<td>• Reimbursement pressure are growing in both US &amp; Europe, disrupting the established players and creating significant decrease in prices</td>
<td>• MedTech companies generally have only limited visibility into pricing performance. In some cases, even lack the tools to generate vital tracking and reporting analysis</td>
</tr>
<tr>
<td>• Further uncertainty lies ahead, with the new EU device regulation in 2020 &amp; price capping imposed by Indian government on essential medical devices</td>
<td>• Negotiating power of hospital systems is growing, and they increasingly contract below GPO prices</td>
<td>• Demand is to pay less for medical devices and see proof of greater value in terms of better patient outcomes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sources: bcg.com, KPMG
2. MedTech consumers/physicians are becoming more demanding

Evolving behavior of MedTech consumers

- Patients/consumers are becoming more proactive; they are actively involved with their healthcare providers in decision making and are very accustomed to asking for the latest device
- Rising consumerism leads to preferences for devices or diagnostics that are more “user-friendly,” reliable and built to last
- More consumers are using technology for health monitoring and are willing to share their data

Physicians* needs

<table>
<thead>
<tr>
<th>Interoperability</th>
<th>Optimized Workflow</th>
<th>Intelligent Augmentation</th>
<th>Data Security &amp; Integrity</th>
</tr>
</thead>
<tbody>
<tr>
<td>83% expected that patient-generated data will be integrated into care delivery in the next 5–10 years</td>
<td>61% highlighted their greatest need for today which is improving routine processes in the clinical practice</td>
<td>64% anticipated that AI will help in predicting &amp; diagnosing diseases as well as prevent acute events</td>
<td>47% wondered about cyberattacks. 69% wanted to know the liability if a technology related medical error occur</td>
</tr>
</tbody>
</table>

*N = 680 physicians

3. Non-traditional players are invading the medical device market; prompting OEMs to re-evaluate their strategies

Amazon partnered with Arcadia, a consultancy group, to launch Choice, an exclusive brand of consumer-use medical devices for diabetes and hypertension management.

Tech giants including Apple and Samsung have recently received FDA clearance for their smartwatches with ECG monitoring app.

**Top growth areas**

- Improved Access to Care
- Healthcare Efficiency Improvements
- Outcomes Improvement
- Preventive Disease Management

**Key implications**

- Driven by the need for continuous innovation and quality care, the medical device sector is likely to see continued entry of non-traditional players over the coming decade.
- It is expected that these new entrants will overcome the regulatory barrier & move upward to higher end products.
- Some of these are partnering with Life Sciences & Genomics and hiring their own healthcare experts, signaling their intent to create new value propositions for patients.

Sources: KPMG, medtechnews.com, mddionline.com
4. Industry competition is becoming fierce due to the growing number of start-ups

Sources: cbinsights, greelight.com

- Medical Device start-ups have raised $10 bn+ for 3 years in a row
- As venture capitalists continue to invest heavily in medical technology, the pressure to innovate is increasing
- Increased competition is leading to the consolidation of more startup companies with the ability to drive MedTech innovations
- Fierce competition from start-ups, new regulatory requirements, and rapidly emerging technologies are creating new complexities and challenges for those operating in this sector

Key implications

Major MedTech start-ups that raised the most money in 2020

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Company name</th>
<th>Total funding ($M)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Tempus</td>
<td>620</td>
</tr>
<tr>
<td>2.</td>
<td>Freenome</td>
<td>507.6</td>
</tr>
<tr>
<td>3.</td>
<td>Recursion</td>
<td>465.4</td>
</tr>
<tr>
<td>4.</td>
<td>CMR Surgical</td>
<td>384.8</td>
</tr>
<tr>
<td>5.</td>
<td>AbCellera Biologics</td>
<td>296.2</td>
</tr>
</tbody>
</table>
5. Growing competition from players located in countries with less complex regulations

Asia-Pacific countries including Vietnam, Malaysia, Thailand, Sri Lanka, and to some extent India, offer less stringent regulations as compared to US & EU. Governments in these countries are incentivizing domestic production and supporting growth of innovative start-ups.

Latin American countries including Chile, Peru, Colombia, and Mexico have friendly regulatory climate. Peru and Colombia take around 30-90 days review time based on device risk. It involves a reasonable set of requirements and straightforward approval process.

Middle eastern countries such as UAE and Israel are witnessing significant growth in number of health technology start-ups. These start-ups are leveraging their less developed & business friendly regulated environment to foster innovation.

Source: who.int
6. The growing need for evidence in medical devices from regulators

Medical device manufacturers are facing extreme pressure by regulatory bodies as well as hospitals to provide evidence to product claims and value propositions – evidence the manufacturers often do not have.

Under the new EU medical device regulations, the amount of clinical data required will be increased significantly, and notified bodies will enforce this need for clinical data.

The European MDR demands that "confirmation of conformity with relevant general safety and performance requirements under the normal conditions of the intended use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit-risk-ratio, shall be based on clinical data providing sufficient clinical evidence."

**Impact**

**Post-market surveillance:** Clinical evidence on safety and efficacy is required for products to retain existing products in market while demonstrating safety and efficacy to improve competitive position and grow market share

**Market access:** Demonstrate comparative value for existing products and label modification (e.g. safety warnings)

**R&D:** Required new process changes due to clinical evidence requirements

Source: emergobyul.com
7. Medical Device cybersecurity vulnerabilities may disrupt future innovation

FDA recently informed about potential cybersecurity vulnerabilities "URGENT/11" for connected medical devices. It is estimated that 97% of OT devices impacted by URGENT/11 have not been patched.

Software issues is emerging as the top reason for medical devices recalls

<table>
<thead>
<tr>
<th>Company</th>
<th>Product type</th>
<th>Units recalled</th>
<th>Reasons for recall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fresenius Kabi</td>
<td>Infusion pump</td>
<td>9,461</td>
<td>Alarms &amp; multiple software errors</td>
</tr>
<tr>
<td>Hamilton Medical</td>
<td>Ventilators</td>
<td>4,338</td>
<td>Potential sporadic message</td>
</tr>
<tr>
<td>Brainlab</td>
<td>Surgical navigation software</td>
<td>60</td>
<td>Inaccurate display during brain surgery</td>
</tr>
<tr>
<td>Medtronic</td>
<td>Surgical navigation software</td>
<td>5,487</td>
<td>Inaccuracies displayed</td>
</tr>
<tr>
<td>Medtronic</td>
<td>Insulin pump</td>
<td>~4,000</td>
<td>Cybersecurity vulnerabilities</td>
</tr>
</tbody>
</table>

Sources: [FDA.gov](https://fda.gov), [herjavecgroup.com](https://herjavecgroup.com), [securitymagazine.com](https://securitymagazine.com)

- **25%** of cyberattacks in healthcare delivery organizations will involve the IoMT
- **67%** probability of a medical device likely to be attacked within next 12 months
- **80%** of MedTech manufacturers believe that medical devices are difficult to secured
- **53%** of device makers believe there is a lack of QA & Testing procedures that lead to vulnerabilities
- **23%** of recalls were caused by software failures, including software anomalies and false results
Key industry trends
The seven challenges impeding the growth of the Medical Device market

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Internet of Medical Things (IoMT)</td>
<td>IoMT is bringing together people, processes, enablers, and data to improve patient outcomes efficiency</td>
</tr>
<tr>
<td>Convergence of Medical Devices</td>
<td>Integration of medical device with patients EMR, wearables, smartphones, and telehealth platforms is delivering key insights for better clinical and operational decision making</td>
</tr>
<tr>
<td>Blockchain</td>
<td>Blockchain is improving the privacy of data sharing across large network of device users and gaining traction across medical device value chain</td>
</tr>
<tr>
<td>Robotics</td>
<td>Robotic surgeries are gaining a lot of momentum in the recent years with multiple new device launches and approvals</td>
</tr>
<tr>
<td>3D/Additive Manufacturing</td>
<td>Significantly reducing the costs of medical implants and surgical tools, and addressing the challenges of recent pandemic</td>
</tr>
</tbody>
</table>
IoMT is helping Medical Device companies move from product suppliers to insightful partners in healthcare

- Improved patient outcomes
- Improved diagnostic & treatment
- Decreased costs
- Remote monitoring of chronic diseases
- Improved disease management
- Enhanced patient experience

IoMT Ecosystem

Source: Deloitte.com
The convergence of medical devices with health information technologies is transforming patient health

Connected medical device collaborations

- Providers (Hospitals/Clinics/Carers)
- Patients
- Connected medical devices
- Analytics platforms
- Payers
- Communication services (cellular/Wi-Fi)

Key enablers driving connected medical device success

- Collaboration between healthcare providers and MedTech is key to the effective deployment of the connected ecosystem
- Adding connectivity to device allows data to be generated on patient’s condition. This will allow medical device companies to understand the exact requirements and provide solutions that deliver value to all stakeholders
- These connected ecosystems act as a common platform to share, aggregate, and view data to drive both clinical and operational value
- Applying advanced analytics to the data generated from this connected environment will help in delivering critical insights and better decision making

Source: Deloitte.com
Applicability of blockchain is spreading across medical device value chain

<table>
<thead>
<tr>
<th>Clinical</th>
<th>Regulatory approval</th>
<th>Manufacturing</th>
<th>Distribution</th>
<th>Marketing</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Patient enrolment</td>
<td>• Data sharing &amp; tracking</td>
<td>• Smart contracts with CROs, CMOs</td>
<td>• Digital track and traceability</td>
<td>• Smart patient health profile</td>
</tr>
<tr>
<td>• E-consent</td>
<td>• Smart contracts</td>
<td>• Manufacturing process control</td>
<td>• Counterfeit protection</td>
<td>• Connected ecosystem</td>
</tr>
<tr>
<td>• Trial documentation</td>
<td>• Records management</td>
<td>• Payment transactions across supply chain</td>
<td>• Inventory management systems</td>
<td>• Secure medical device data</td>
</tr>
<tr>
<td>• Data sharing</td>
<td>• IP registration and exchange</td>
<td>• Regulatory compliance requirements</td>
<td>• Targeted recalls</td>
<td>• Preventive device maintenance</td>
</tr>
<tr>
<td></td>
<td>• Proof of existence for patents filing</td>
<td></td>
<td>• Payment transactions</td>
<td>• Health coin and health</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>insurance</td>
</tr>
</tbody>
</table>

Recently, in January 2020, four Swiss hospitals along with two medical device suppliers Anandic System Medical AG and ITRIS Medical AG announced successful processing on a trial of medical device orders via the Blockchain.

Philips partnered with Blockchain specialist Gem and launched Gem Health a network for developing applications & shared infrastructure for a patient-centric approach to healthcare.

Sources: KPMG, healthmanagement.org, medexchange.io
Surgical Robotic market is witnessing multiple new launches; expected to grow to $11 bn in size by 2025

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2019</td>
<td>Medtronic received FDA clearance for its cranial robotic platform</td>
</tr>
<tr>
<td>July 2020</td>
<td>Smith+Nephew launched its new generation handheld robotics platform - the CORI Surgical System. The device has received FDA clearance for sale in the US.</td>
</tr>
<tr>
<td>November 2020</td>
<td>Ganymed Robotics announced the successful completion of functional prototype tests of its surgical robotic assistant for total knee arthroplasty</td>
</tr>
<tr>
<td>December 2020</td>
<td>Sysmex Corporation announced the launch of hinotori Surgical Robot System, a surgical robot unit for medical institutions in Japan</td>
</tr>
<tr>
<td>January 2021</td>
<td>DePuy Synthes received 510(k) FDA clearance for VELYS Robotic-Assisted Solution designed for use with the ATTUNE Total Knee System</td>
</tr>
</tbody>
</table>

Sources: sysmex.co.jp, prnewswire, med-technews1, medtechnews2, medtechnews3
3D-Printing is providing solutions for the challenges posed by COVID-19

**Protolab** has worked with a team at the University of Minnesota to develop, a low-cost ventilator.

The ventilator relies on a motor to pump manual "Ambu" bags so that hospitals could produce their own in the event of life-or-death shortages.

**Isinnova**, a Brescia based engineering company met the shortage of respiratory valves

3D printing was used to connect the COVID-19 patients to the machines to save their lives.

**Formlabs**, a 3D-printer maker, worked with medical experts at USF Health in Tampa and Northwell Health to rapidly develop and test nasal swabs.

Source: greyb.com
Technology-driven transformation
Recent highlights

- In April 2019, GE Healthcare integrated its Edison AI platform with American College of Radiology’s AI-LABTM, providing ACR members and other radiology professionals with connectivity to valuable Edison AI services.
- Edison is a tool that tracks the source and usage of data in AI development and simplifies radiologists’ ability to create, validate and deploy compliant algorithms with partner institutions.

- BioTelemetry deals in remote cardiac diagnostics and monitoring with portfolios in AI based analytics & services and wearable heart monitors.
- This helped the company in strengthening its AI capabilities.
Medical Devices as a Service Provider

Medical device manufacturers are delivering optimized care through holistic solutions, including hardware, software, and services.

Healthcare providers are increasingly facing margin and growth pressures; increasingly seeking solutions that deliver better and more consistent outcomes at reduced costs.

Medical device manufacturers are playing significant roles in collaborating with hospitals to deliver better patient care.

**Positioning relative to core product or portfolio offering**

Some solutions are linked or adjacent to core product or portfolio offerings (e.g., clinical-support tools, Cath-lab outsourcing).

Others are agnostic to the core offer and have the potential to be stand-alone solutions (e.g., management and consulting services).

**Key services**

- Clinical Decision-Support Tools
- Cath-lab Outsourcing
- Population Health Management
- Treatment Planning Tools
- Workflow Management/Consulting Services

**Primary stakeholder for solutions**

Few solutions (e.g., treatment planning tools) are primarily targeted towards existing stakeholders including surgeons and providers.

Others (e.g., population health management & work-flow solutions) are primarily targeted towards new stakeholders including patients, payers, & broader health-system executives.

Sources: www.mckinsey.com
Medical Devices as a Data & Analytics Partners

There is an increase in medical devices being used for self-management and reporting pushed into home with the intended benefits of patient convenience and low healthcare cost.

Medtech manufacturers are increasingly focusing on designing devices that drives patient self-monitoring and treatment.

Recent highlights

Tandem’s **new interoperable insulin pump** can be used with different components that makes up diabetes therapy systems, allowing patients to **customize their diabetes management** to individual device preferences.

Bose hearing aids – the first FDA approved hearing aids are known as the **self-fitting air-conduction hearing aid**. No preprogramming or hearing test is necessary. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.

Sources: [www.businesswire.com](http://www.businesswire.com), [techcrunch.com](http://techcrunch.com)
Ensuring connected device “safety” will improve innovation

Mining, managing and analyzing a vast array of data from medical grade wearables, connected imaging devices and monitoring devices is a key part of deriving value from the IoMT.

- Industry-wide standards & cybersecurity by design
- Improved awareness, education & training
- Investments in cybersecurity incident response processes
- Defining all the security requirements of the product

Recent highlights

- In Feb 2020, GE launched new medical device cybersecurity offering, Skeye to protect connected medical devices at health systems
- It utilizes AI-enabled tools together with the security operations center to analyze, monitor and help manage cybersecurity vulnerabilities

- In Nov. 2020, Philips partnered with CyberMDX, a leader in connected medical device security, and introduce Philips Cybersecurity Services to protect connected medical systems and devices
- The services will initially be deployed in the U.S., with expansion to other geographies planned for 2021

Sources: www.mpo-mag.com, philips.com, ge.com
3D printing is addressing the Medical Device costs challenges

Cost savings

- Over 90% of the top medical device companies use 3D printing to develop accurate prototypes of medical devices, as well as fixtures and jigs to simplify testing.
- One of the medical device manufacturers reported cost reduction of up to 70%. Another medical research institute estimated that if they use 3D printed models in 10-15% of cases, it could save up to $1,750,000 a year.

Affordable prosthetics

- Custom-fit prosthetics are often expensive and only accessible to patients with insurance in developed countries.
- Prosthetics are increasingly taking advantage of 3D printing’s flexible design to mitigate these financial barriers.

Surgical instruments

- Using 3D printing to produce surgical instruments is an accurate and cost-effective way to quickly manufacture highly-demanded medical supplies.
- It is easy to modify designs for surgical needs, even for complex instruments.

Source: docwirenews.com
Surgical robotics market is flourishing with multiple competitors adopting differentiation strategy

- Intuitive Surgical’s minimal access surgery (MAS) robot da Vinci rule the market ever since its launched. A 32% increase is reported in Intuitive Surgical’s global procedures from 2017 to 2018
- However, now, over two decades after it first entered the market, da Vinci’s patents are expiring. This expire is opening market to multiple new competitors

- CMR Surgical is considered as a key challenger to Intuitive Surgical’s market dominance
  - It raised over 236 million to finance the global commercialization of its MAS Versius robotic system
  - Its modular design and competitive cost are factors that should help CMR gain a larger market share in the coming years

- Zimmer Biomet is competing with like Stryker in robot assisted knee surgery through its Rosa platform
  - As of August 2020, the company had 150 Rosa knee systems placed around the world
  - The company acquired the initial Rosa technology through its roughly $132 million purchase of Medtech in 2016

- The company has made a push into automated intelligence
  - TransEnterix’s Senhance System boasts haptic feedback, surgeon camera control via eye sensing and improved ergonomics
  - The company received both CE & US FDA clearance for marketing

Sources: www.medicaldevice, medicaldesignandoutsourcing
Blockchain has the ability to ensure data privacy across connected medical ecosystem

Sources: mpo-mag.com, philips.com, ge.com

<table>
<thead>
<tr>
<th>Interoperability</th>
<th>Optimized workflow</th>
<th>Intelligent augmentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Falsifying data becomes impossible, and health information, medical test dates and results, billing &amp; payments are immutably and automatically recorded, preventing fraudulent activity</td>
<td>Improved data sharing process can be achieved through smooth coordination between multiple care providers, streamlined verification processes and automated claims adjudication based on immutable, complete records</td>
<td>Blockchain technology guarantees data prevalence in healthcare and allows trust without the need for third parties. A high degree of privacy and safety is obtained by authenticating and securely storing data</td>
</tr>
</tbody>
</table>
Software as Medical Device (SaMD) market overview
Global Software as a Medical Device market is expected to grow to \(~$86.5\) bn by 2027

Key insights

- The software as a medical device (SaMD) market is projected to grow at a CAGR of 21.9% during the forecast period of 2019-2027
- The market is anticipated to gain \(~$68\) billion by the end of 2027 end
- This trend is driven by product differentiation being increasingly in software as well as the introduction of cloud-based and holistic solutions

Sources: FDA, Knowledge Sourcing
Software as a Medical Device technology is empowering patients; providing more control over their own health

<table>
<thead>
<tr>
<th>Portability &amp; affordability</th>
<th>SaMD is helping revolutionize the medical device industry and the healthcare industry. The technology makes medical devices smaller, more portable, and more affordable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment ownership</td>
<td>The technology gives patients more access to medical devices, thus giving patients more ownership over their treatment and overall health.</td>
</tr>
<tr>
<td>Real-time analysis</td>
<td>The technology helps medical professionals get vital health information in real-time instead of only at visits.</td>
</tr>
</tbody>
</table>

Sources: McKinsey, Analytics Insights, Knowledge Sourcing, boundarysys
## Trends impacting the SaMD market

<table>
<thead>
<tr>
<th>SaMP trends</th>
<th>Description</th>
<th>Impact on software in MedTech</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Integrated solutions</strong></td>
<td>Integrated medical ecosystems with shared information across medical devices and electronic health record (EHR) systems to allow for continuous care and remote management</td>
<td>Interoperability, software quality and cyber security become a major concern as connected medical devices are vulnerable to integration issues as well as cyber security and hacking concerns</td>
</tr>
<tr>
<td><strong>Regulations</strong></td>
<td>Regulatory bodies continue to implement stricter guidelines for medical device software, development processes, design control, and quality standards required prior to release</td>
<td>Developers must adopt modular architectures that allow for faster validation, collaborative development, easier integration and improved quality</td>
</tr>
<tr>
<td><strong>Smarter devices</strong></td>
<td>Multifunctional devices, combining multiple sensors, processing capabilities with customizable setup and preferences and a personalized user interface</td>
<td>Software is becoming the differentiator for medical device manufacturers, with increased focus on quality as products become more complex with inter-related features and new functions</td>
</tr>
<tr>
<td><strong>Real-time analytics</strong></td>
<td>Software systems that perform real-time, predictive analytics and machine learning to determine trends and risks, and to enable immediate and personalized medicine</td>
<td>Increased product complexity that requires new and different skill sets such as advanced analytics and algorithms, patient care operations, cloud, etc.</td>
</tr>
</tbody>
</table>

Source: McKinsey
Recent regulatory insights
In March 2017, the EU Council adopted new medical device regulations (MDR) in order to reform existing medical device and in-vitro diagnostics regulations. Under the new guidelines, all medical devices will need to undergo safety & performance assessment before they can be marketed in Europe.

### UK Registration Process

#### May 2021
- MDR date of application

#### May 2022
- EC certificates of conformity issued before May 27, 2017 expire

#### May 2024
- Required for all EC certificates issued 5 years from the issue/renewal date or 4 years from the MDR date of application

#### May 2025
- Devices certified under the MDD can no longer be sold or distributed

From January 2021, UK adopted new medical device registration process and will not be adopting the EU MDR.

- Starting from Jan 1, 2021, a new mark was introduced in the UK – the UKCA (K Conformity Assessed) and it will be required on all devices placed on the Great Britain market from July 1, 2023
- EU will no longer recognize UK Notified Bodies, and they will not be able to issue CE certificates
- New UK regulations requires all medical devices available on the UK market to be registered with the MHRA
- Class I medical devices, custom-made devices and IVDs are required to register immediately, with other devices awarded a grace period until either May 1 or September 1, 2021

Sources: orienstat, hsfnotes, mobihealthnews
### Impact of EU MDR on Medical Device Manufacturers

<table>
<thead>
<tr>
<th>Reclassification or up-classification of devices</th>
<th>Elevated clinical testing requirements</th>
<th>Focus on post-market surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under the MDR and IVDR, changes will made to the way the medical devices are classified. Requirements will be scrutinized based on risk to the patients, for e.g., certain devices that come into contact with the spinal cord will move up from class II to class III. Reclassification will require costly certification process for new &amp; existing products.</td>
<td>For medical devices, the new regulations require reassessment of clinical data for devices already on the market. If the data do not meet the new requirements, devices will be required to undergo additional testing to be recertified, increasing the expense of maintaining legacy devices. Due to reclassification of IVDs, device makers that have not previously been required to perform clinical testing will have to develop the ability to do so.</td>
<td>Under the new IVDR and MDR there will be an increased emphasis on post-market surveillance. This includes proactively monitoring device performance for recertification, rapid reporting of safety incidents, and annual safety updates for higher-risk class devices.</td>
</tr>
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**Key regulatory highlights of 2020**

**The US**

- In January 2021, US FDA released “Artificial Intelligence and Machine Learning (AI/ML) Software as a Medical Device Action Plan” in response to stakeholder feedback on its April 2020 discussion paper
- It outlines a multi-pronged approach to advance the Agency’s oversight of AI/ML-based medical software
- In September 2020, US FDA launched Digital Health Center of Excellence within the Center for Devices and Radiological Health (CDRH)
- This was intended to increase agency’s efforts towards advancements in digital health technology, including mobile health devices, SaMD, wearables when used as a medical device, and technologies used to study medical products
- US FDA issued Emergency Use Authorizations (EUA) for medical device including IVD test kits for COVID-19 testing and PPE such as filtering facepiece respirators
- In addition, FDA released final guidance on ventilator devices that facilitates EUA designations for these products to treat COVID-19 patients


**In India**, Medical device trade margins is set to capped at 30%. Cardiac stents, drug-eluting stents, and intra-uterine devices are included in the National List of Essential Medicines and are, therefore, subject to notified price caps. Stents and knee implants were the latest to be brought under control.

**China’s Center for Medical Device Evaluation** recently released new procedures for device registration in 2020. This include increased standardization of filing review process and new withdrawal and re-submission procedures for up-classified devices.

**In Brazil**, a new ordinance was published by INMETRO which requires additional registration prerequisite for most electro-medical devices subject to IEC 60601, along with some other device types such as hypodermic needles, breast implants, surgical gloves & syringes.

**In 2019, Australia’s Therapeutic Goods Administration** released a three-pronged proposal aimed at boosting the country’s oversight of medical devices, more tightly regulating how medical devices enter the AU market, strengthening post-market monitoring and publishing more information on how decisions are made for higher risk devices.
Get in touch!
We’re happy to help with any questions

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