



# The EU Medical Device Regulation and the U.S. Medical Device Industry

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## *Abstract*

*The United States has long had the world's most successful medical device (or medtech) industry, with the European Union (EU) serving as its largest export market. The trading bloc's reputation for relatively timely market approvals has long benefited these U.S. manufacturers. However, the EU's soon-to-be-implemented Medical Device Regulation (MDR)—an overhaul of the previous medtech regulatory regime—may present a number of obstacles for U.S. and other medtech firms that could limit their access to a critical market.*

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## Introduction

Regulatory practices are critical determinants of the overall ability of firms producing medical devices (medtech) to sell their goods competitively in a given country. Regulations shape market access for foreign producers and influence decisions about pricing products within these markets.<sup>1</sup> For certain medical devices, such as orthopedic implants and diagnostic technologies, the potentially high health risks posed to patients suggest the need for countries to maintain strict regulatory regimes to protect consumers and ensure their confidence.<sup>2</sup> At the same time, regulatory procedures that significantly depart from international best practices can restrict trade and delay vital treatments for patients.

The United States has the world's largest medtech industry, by sales, and the European Union (EU) has long been its largest export market. The success of U.S. medtech firms in Europe has largely stemmed from an understanding of EU regulations. Further, the EU has enjoyed a reputation for having one of the world's most timely paths to market for medtech goods. However, on April 5, 2017, the European Parliament and Council released stricter regulatory requirements in the form of its updated Medical Device Regulation (MDR), which will replace the current EU Medical Device Directive (MDD) next year. The MDD, which has been in force for over 20 years, governs the approval of medical devices for introduction into the EU market, as well as of the certified bodies that certify regulatory approval of medical device firms.

Slated to enter into force on May 26, 2020, the MDR is expected to restructure how the EU approves medical devices. It will affect a wide range of steps in the process, from submission of clinical trial data for lower-risk medical products and conformity assessment procedures to labeling requirements and post-market surveillance of products. This article explores the potential challenges facing U.S. medtech firms as they attempt to navigate the MDR.

### The Global Medtech Industry Is Led by the United States

Global medical device production is largely led by the United States, which boasted 10 of the world's top 15 producers during 2018 and has captured more than one-third of global market share in recent years (table 1). Leading original equipment manufacturers (OEMs) of medical devices generate roughly half their sales outside the United States.<sup>3</sup> Europe has accounted for roughly 30 percent of these sales in recent years.<sup>4</sup> The EU alone represented nearly 40 percent (\$21.6 billion) of U.S. medtech exports in 2018.<sup>5</sup> Moreover, during April 2009–May 2017, the trading bloc captured the second-largest share of foreign direct investment (FDI) from the U.S. medical device sector (table 2).

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<sup>1</sup> Herman, Horowitz, and Torsekar, "Competitive Conditions Affecting Medtech Trade," September 2018.

<sup>2</sup> Torsekar, "China Climbs the Global Value Chains," March 2018.

<sup>3</sup> Snyder, *Healthcare Equipment and Supplies*, May 2016, 50.

<sup>4</sup> S&P, *Healthcare: Products and Supplies*, February 2014, 19.

<sup>5</sup> IHS Markit, Global Trade Atlas database (accessed June 20, 2019).

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**Table 1:** The world's top 15 medical device manufacturers in 2018 by revenue, headquarters, and 2017 market share

Company	Headquartered	Revenue (billion \$)	Global market share (%)
Medtronic	Ireland	30.5	7
Johnson & Johnson	U.S.	26.9	6
GE Healthcare	U.S.	19.7	5
Abbott Laboratories	U.S.	18.9	4
Phillips	Netherlands	16.1	4
Becton Dickinson	U.S.	15.9	4
Cardinal Health	U.S.	15.6	4
Siemens Healthineers	Germany	15.5	4
Stryker	U.S.	13.6	3
Baxter	U.S.	11.1	3
Boston Scientific	U.S.	9.8	2
Danaher	U.S.	9.1	2
EssilorLuxxotica	France	8.5	2
Zimmer Biomet	U.S.	7.9	2
B. Braun	Germany	7.9	2
Top 15 totals	n/a	227.0	52
All other	n/a	206.7	48
Total industry	n/a	433.7	100.0

Source: Fenske, "Top 30 Global Medical Device Companies," July 30, 2019; Snyder, *Healthcare Equipment and Supplies*, May 2017.

Note: Estimates of market share were based on estimated total industry revenues for 2018 from Statista, "Total Global Medical Technology Revenue," October 25, 2018.

**Table 2:** Share of new U.S. FDI projects, by region, January 2009–August 2017

Region	Percent	Number of Projects
Asia-Pacific	39	395
Europe	33	334
North America	19	192
Other	9	92
Total	100	1,013

Source: Compiled by authors from Financial Times, fDiMarkets database (accessed October 12, 2017).

## Overview of Medical Device Regulations

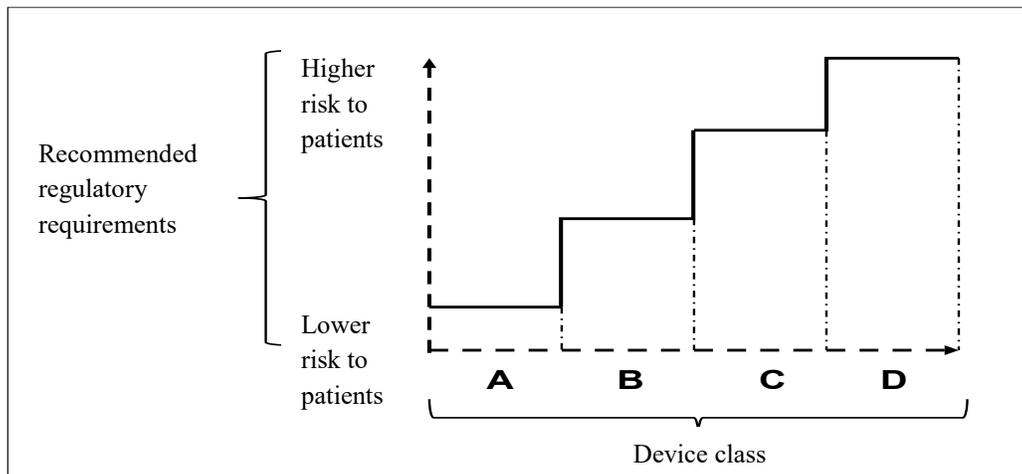
Globally, nearly all major markets apply a risk-based classification system to regulate medtech goods, similar to the structures recommended by the Global Harmonization Task Force (GHTF), a voluntary international association that was aimed at harmonizing international medical device standards. Specifically, the GHTF recommended dividing medical devices into four categories—A, B, C, and D—based on the relative harm they potentially pose to patients; regulatory requirements were ideally supposed to become stricter in accordance with the relative device risk (figure 1).<sup>6</sup> Though the GHTF was disbanded in December 2012, it has since been replaced by

<sup>6</sup> However, variations in the categorization of devices varies across countries. In the United States, the Food and Drug Administration (FDA) identifies three classes of medtech, which range from basic hospital supplies and other

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the International Medical Device Regulators Forum (IMDRF), which adheres to the recommendations of its predecessor.

**Figure 1:** Conceptual illustration of the device class and corresponding GHTF recommended regulatory requirements.



Source: GHTF, "Principles of Conformity Assessment for Medical Devices," November 2, 2012, 11.

For the highest-risk devices, most countries require clinical trials as an additional assurance of safety. These trials require the manufacturer to accumulate and submit data on the use of the specific device on patients, and as a result can be lengthy. Generally speaking, devices that are similar to those already approved for sale are permitted to bypass clinical trials and gain approval faster than novel, high-risk devices.

In addition to using a risk-based approach to medical device classification, international best practices commonly require companies to conduct conformity assessments of their products before they can gain market approval. These conformity assessment procedures are intended to provide evidence of the safety and reliability of a given medical device by detailing the sampling, testing, inspection, certification, and registration requirements to gain approval. According to the GHTF, conformity assessment principles include the following elements:

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disposables (class I), to therapeutics and other devices that carry slightly elevated health risks but are similar to existing devices on the market (class II), to diagnostic devices which exhibit a high risk of injury or illness to a patient (class III).

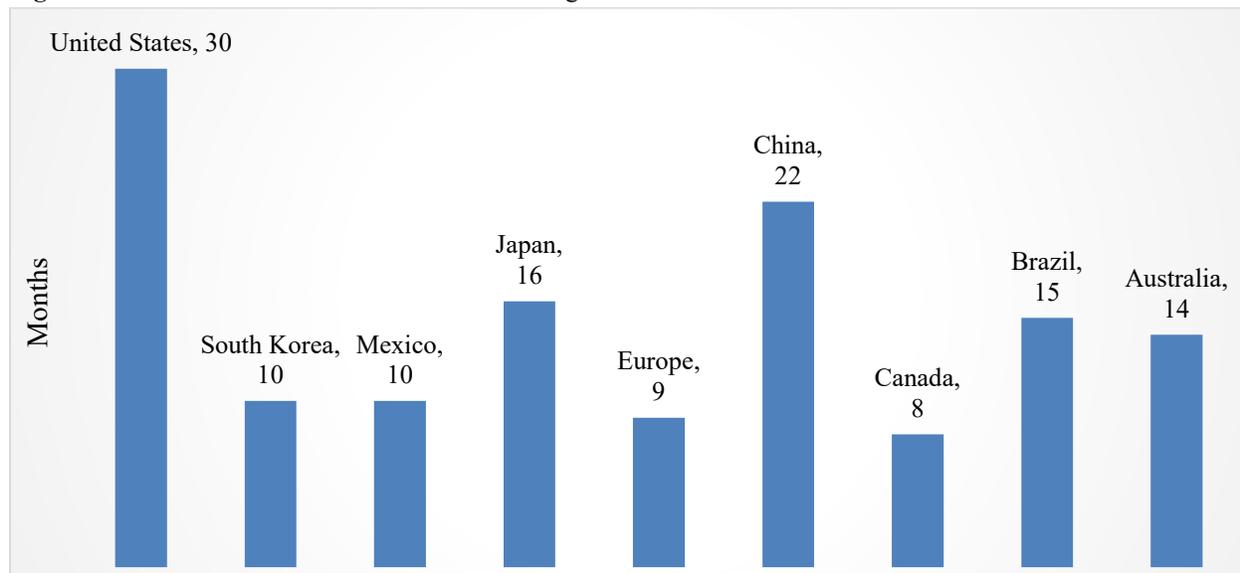
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- a quality management system for class C and D devices verified by audits from registration authorities (RAs) and/or conformity assessment bodies (CABs)<sup>7</sup>
- post-market surveillance systems
- technical documentation of the product
- a declaration of conformity
- registration of manufacturers and their medical devices RAs<sup>8</sup>

The results of the conformity assessments are commonly verified by the relevant RAs and/or CABs within a given jurisdiction.<sup>9</sup>

Despite the wide adoption of international best practices, variations in the application of these standards can lead to variations in the time to market for medtech manufacturers.<sup>10</sup> The EU has consistently ranked favorably as having a relatively short time to market—three to nine months—for high-risk devices. This has allowed U.S. medical device manufacturers to sell many of their products in the EU market even before the products can be sold in the United States or other major markets.<sup>11</sup> The United States and China rank among countries with the highest maximum time to market (figure 2).

**Figure 2:** Maximum estimated time to market for high risk devices



Source: Emergo Group, “Resource Library for Professionals” (accessed June 20, 2019).

<sup>7</sup> Broadly speaking, both entities ensure that a manufacturer has fulfilled the technical regulations or standards of a given jurisdiction and, in some cases, takes actions to ensure compliance. Technical regulations refer to documents which describe product characteristics and detail production methods for which compliance is mandatory; standards are similar to technical regulations, but compliance with production methods is optional.

<sup>8</sup> GHTF, “Principles of Conformity Assessment for Medical Devices,” November 2, 2012, 7.

<sup>9</sup> GHTF, “Principles of Conformity Assessment for Medical Devices,” November 2, 2012.

<sup>10</sup> For example, the imposition of duplicative, country-specific standards (e.g., labeling requirements that require information that is not directly related to product safety) can translate into delayed market access for exporters.

<sup>11</sup> Emergo Group, “Resource Library for Professionals” (accessed June 20, 2019).

## Current EU Regulations: The Medical Device Directive

Since 1994, the regulation of medtech in the EU has been governed by the Medical Device Directive (MDD). Consistent with the international best practices listed above, the EU has applied a risk-based classification system to medtech products, though it includes five classes—I nonsterile, I sterile, IIa, IIb, and III—rather than four (table 3).<sup>12</sup>

**Table 3:** Classification of medical devices under the MDD

Class	Risk Level	Description of Class Level	Examples
I Non-sterile	Low risk	Non-sterile or does not have a measuring function	Volumetric urine bags, tongue depressors
I Sterile	Low/medium risk	Must be sterile and/or provide a measuring function	Bandage dressings, scalpels
IIa	Medium risk	Invasive device intended for short-term use, except if used in mouth or ear (then Class I)	Syringes, nebulizers
IIb	Medium/high risk	Invasive device intended for long-term use, except if used in mouth or ear (then Class IIa), or invasive devices intended for transient use with exceptions	Defibrillators, hemodialyzers, incubators, lung ventilators
III	High risk	All devices incorporating a substance which if used separately can be considered a medical product, blood derivatives, or utilize animal tissues of derivatives. Also any device intended to control or monitor blood circulation or the central nervous system.	Heart monitors, breast implants, catheters, stints, bioactive implantable devices, IUDs

Source: MDD, Annex IX; Kobridge, “EU MDR Compliance with European Directives or Regulations,” n.d.

Additionally, the trading bloc has stipulated various conformity assessments, the successful completion of which earns manufacturers a *Conformité Européene* mark (CE or “European Conformity” mark). Once it has received a CE mark, a device can be sold on the market in any EU member state or European Free Trade Area country<sup>13</sup> without modification. However, there may be additional requirements based on EU member state regulations that manufacturers must

<sup>12</sup> In vitro and active implantable medical devices are not classified using the device risk class system. IVDD Article 9 divides in vitro medical devices into three groups based on lists of indications laid out in Annex II; these lists specify different conformity assessment options for each group. EUR-Lex, “Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices,” October 27, 1998. Active implantable medical devices are treated as a single class of devices, with regulatory controls very similar to those of class III medical devices. EUR-Lex, “Council Directive 90/385/EEC of 20 June 1990 on the Approximation of the Laws of the Member States relating to Active Implantable Medical Devices,” June 1990.

<sup>13</sup> A small number of countries (Norway, Iceland, Liechtenstein, Turkey, and Switzerland) are not EU members but are members of many European agreements that allow cross-border trade with minimal restrictions. These associated countries participate in the European single market and are bound by the EU rules for that market if they want to participate in it, but do not have representation within the decision-making structures of the EU. Industry representative, interview by USITC staff, June 2016. Additionally, according to interviews with regulatory experts, the associated countries were as involved as any member state in the creation of the commission proposal for the MDR, but have no more voice in the policy process now that the proposal has been published. Much of the input that the associated countries have is through informal communications with the member states involved with the negotiations. For example, one expert noted that Germany has some communication with Switzerland outside of the official discussions, and can pass on Swiss concerns by that route if necessary. Industry representative, interview by USITC staff, April 2016.

comply with before starting sales or distribution, such as labeling requirements or individual country registration requirements. In addition, any manufacturer that places a device on the market in an EU member state but does not have a registered place of business in the EU must designate an Authorized Representative to act on its behalf. The Authorized Representative serves as a point of contact for the regulatory authorities, especially in case of emergencies.<sup>14</sup> Once a device is on the market, manufacturers are expected to comply with regulatory requirements for market surveillance and for adverse events.<sup>15</sup> A CE mark is valid for five years before it must be renewed.

For medium- and high-risk devices, the CE mark is provided by a “notified body” (NB)—a private organization that is authorized to audit and inspect manufacturers’ facilities and processes to certify that they comply with EU directives. In addition, once a device is placed on the market, the manufacturer is subject to periodic audits to confirm compliance with regulations.<sup>16</sup>

## What Is the EU MDR?

The EU Medical Device Regulation repealed and replaced the existing MDD, and will cover all medical devices for the EU market (with an expanded definition that includes products not previously considered medical devices).<sup>17</sup> While the MDR formally went into effect on May 26, 2017, the majority of its provisions that relate to the actual approval of medical devices will go into force on May 26, 2020.<sup>18</sup>

The overarching purpose of the EU MDR is to update the regulatory framework for the EU medical device market (table 4). Additionally, the MDR was designed to increase transparency in the market while providing increased regulatory certainty and establishing a more consistent regulatory process.<sup>19</sup> Concerns had been raised by both EU regulators and market participants that the current regulatory framework did not ensure consistency across EU member states. This inconsistency led to allegations of regulatory arbitrage for medical devices (i.e., the deliberate registration of devices in EU countries with weaker enforcement of regulatory procedures).<sup>20</sup>

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<sup>14</sup> European Commission, DG Health and Consumers, “Guideline for Authorized Representatives,” January 2012.

<sup>15</sup> European Commission, DG Health and Consumers, “Guideline for Authorized Representatives,” January 2012.

<sup>16</sup> EUR-Lex, “Commission Recommendation of 24 September 2013,” September 25, 2013, 27–35.

<sup>17</sup> Directives and regulations are slightly different in practice. Directives establish results that must be achieved within the EU, but each member state is able to determine how it translates directives into national laws. Regulations confer a binding legal obligation on every member state and enter into force on the same date across the EU. USDA, FAS, “United States Mission to the European Union,” December 21, 2016.

<sup>18</sup> Crützen and Michaux, “Europe—Key Dates and Roadmap for Implementation,” December 1, 2017.

<sup>19</sup> Rose, “Top 10 Challenges of the New MDR,” June 22, 2017.

<sup>20</sup> For example, several EU members from eastern Europe ranked among the world’s least trade restrictive markets for medtech. They included Lithuania (ranked as number 5), Slovenia (16), Latvia (18), and Bulgaria (19). Meanwhile, the EU’s largest markets ranked much higher: Germany (69), United Kingdom (100), and France (77). This seems to suggest meaningful variations in the relative ease of entry into these respective markets. Herman, Horowitz, and Torsekar, “Competitive Conditions Affecting U.S. Exports of Medical Technology,” August 2018.

**Table 4:** Major changes from the MDD to MDR

<b>Major Regulatory Stage</b>	<b>Change from MDD to MDR</b>
Research and clinical trials	Tightens existing standards for research and clinical trials; creates a higher bar for the use of certain research data in establishing safety and use for medical devices. Clinical trials will now be required for lower-risk products and a wider variety of medical devices.
Conformity assessment procedures	Requires the use of unique device identification (UDI) codes for medical devices, and requires CE certifications for a variety of products not previously covered by the MDD.
Post-market surveillance	Under the MDR, firms producing more advanced products that fall under classes II or III will be required to conduct at least yearly assessments of their products' operation in the EU market and of any developments that may impact the effectiveness or health outcomes of their devices. These firms must also collect more data and operate more transparently.

Source: compiled by authors

Finally, the MDR is intended to improve the regulatory approval and enforcement process. For example, the 2012 recall of tens of thousands of faulty breast implants from a French medical device manufacturer (the PIP controversy<sup>21</sup>) due to the use of industrial-grade rather than medical-grade silicone spurred significant public health concerns and highlighted a need for a stronger regulatory approval and enforcement process for medical devices.<sup>22</sup>

Many of these developments informed some of the key changes that occurred in EU medical device law with the transition from the MDD to MDR. For example, requirements that consumers affected by defective medical devices be compensated even if the manufacturer is unable to do so are new in the MDR.<sup>23</sup> Further, MDR's imposition of mandatory, unannounced audits of medical device firms and NBS<sup>24</sup> can be directly connected to gaps revealed by the breast implant scandal.<sup>25</sup> Additionally, modern medical devices are becoming increasingly technologically advanced since the previous MDD came into force in 1993, with substantially more data collected and transmitted; recognition of this change informed the new data-entry requirements of the MDR.

The MDR impacts nearly every stage of the approval process for bringing medical devices to the market. This section will lay out these changes as they relate to major stages of the medical device approval process, including conducting research and clinical trials, performing conformity

<sup>21</sup> The Poly Implant Prothèse (PIP) controversy was a 2014 recall of tens of thousands of breast implants made by a French manufacturer that had used industrial silicone in some of its breast implants, leading to at least one confirmed death and several injuries. The firm went into bankruptcy, thousands of EU patients had to undergo implant removal surgery, and the scandal was widely viewed to have prompted the overhaul of EU medical device regulations, leading to the MDR. European Commission, "Restoring Confidence in Medical Devices. Action Plan," June 20, 2014.

<sup>22</sup> Interview with industry representative, August 24, 2018.

<sup>23</sup> EC, EU Medical Device Regulation 2017, Article 69.

<sup>24</sup> EC, EU Medical Device Regulation 2017, Introduction paragraph 52, Article 44.7, Article 93.3.b.

<sup>25</sup> EC, "Restoring Confidence in Medical Devices. Action Plan," June 20, 2014.

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assessment procedures for CE bodies, carrying out post-market surveillance, and recalling devices already on the market.

## **Research and Clinical Trials**

In addition to adhering to conformity assessments, some devices previously exempted from clinical trials under the MDD will now be required to undergo them under the MDR. Broadly, the changes instituted by the MDR on research and clinical trials will tighten the existing standards, expand the number and types of items required to go through clinical trials, and increase the amount of data needed to satisfy regulatory requirements before receiving CE approval.

The standards now applicable to clinical trials in the European Union under the MDD have been refined by the MDR, reducing the ambiguity that had previously typified the standards. As one example, “clinical performance” is not defined under the MDD. Under the MDR, “clinical performance” is defined as “the ability of a device, resulting from any direct or indirect medical effects that stem from its technical or functional characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients when used as intended by the manufacturer.” This tightening of language about clinical trials and of the parameters within which they can operate is extensive under the MDR, including new definitions of clinical evaluation, data, evidence, and benefit, as well as a distinction between innovative and derivative devices.

The obligations for medical device manufacturers under the MDR also include wider requirements for clinical trials. Under the MDD, firms could qualify their products for the CE marking procedure either using clinical trials or tests, or a review of existing medical device literature, unless the device fell into the most sensitive, class III category. With the MDR, the requirement of a clinical trial rather than a medical device literature review is likely to extend to class IIa and IIb devices.<sup>26</sup> Additionally, many devices that have previously gone through clinical trials under the former MDD regulatory framework may have to undergo a new test, called a “fitness for use” test, which ensures that previously used data are rigorous enough to meet the MDR standard. This has led many firms to consider taking older medical devices off the market, fearing that they will not be able to meet the new standards of the MDR with older test data and that it is not worth the effort to gather new data.<sup>27</sup>

The MDR also extends the jurisdiction of medical device regulation to a wider range of products, requiring certain products to undergo clinical tests or medical device literature reviews that had previously not been required to face such scrutiny before attaining EU market access. Products that are now, for purposes of the MDR, viewed as medical devices include:

- Contact lenses and other products that are used in the eye
- Products introduced to the body to modify anatomy surgically

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<sup>26</sup> Industry representative, interview by USITC staff, Washington, DC, August 24, 2018.

<sup>27</sup> Industry representative, interview by USITC staff, Washington, DC, August 24, 2018.

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- Products used for facial or other subcutaneous filling (often botox)
- Equipment for liposuction and lipoplasty
- Skin treatment equipment for tattoo and hair removal
- Electrical or magnetic equipment for brain stimulation
- Products designed for cleaning, disinfecting, or sterilizing other medical devices
- Accessories to enable medical devices (examples can include sterilization nets and software to create images of expected effects of implants)
- Devices for control and support of conception (which includes condoms)

While not all these items will require clinical tests and CE certifications, others will (particularly conception devices and cleaning products). None of these devices had previously fallen under EU-wide medical device regulations, creating a new series of regulatory steps for certain device manufacturers to take in order to access the EU market.

Finally, devices that had been offered in the European market under the previous MDD regulations must fulfill the new requirements under the MDR, following a transition period. Under Annex I of the MDR, many of the requirements of the MDD have been carried over using similar or the same language (e.g., requirements that a device must be “designed and manufactured in such a way that safety of patients and users shall not be compromised”). However, there are several changes of note: there are likely to be new requirements—established by a newly created regulatory body—on the use of phthalates, carcinogenic, mutagenic, or toxic for reproduction (CMR) substances, and endocrine-disrupting substances in medical devices. Additionally, there will be new requirements for the use of substances of a “toxicological concern.” Special attention will now be given to nanomaterials used in medical devices, and labeling for sterile and for single and multi-use devices will also be changed.

### **Conformity Assessment Procedures for CE Marking**

As explained above, the CE marking certifies that a product has successfully fulfilled all EU-level regulatory requirements for a product to be offered to the EU market. Given the strictness of medical device regulation and the risk associated with offering products, the process for gaining CE certification for medical devices in the EU is rigorous.

About 60 organizations in the European Union presently serve as CE “notified bodies” (NBs) for medical devices under the MDD.<sup>28</sup> These organizations provide the certification for any medical device manufacturer that seeks to sell its products to any country in the EU market. The MDR will require the recertification of almost all NBs interested in serving as official certifiers of future EU regulations. As the section below will illustrate, there is currently uncertainty about whether the organizations currently serving as NBs will have the institutional capacity or the approval of the necessary EU bodies to continue serving as NBs under the new EU framework. These concerns have been aggravated by the recently announced withdrawal of nine NBs from

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<sup>28</sup> Oriol, “Number of Notified Bodies Pursuing MDR and IVDR Certification,” March 3, 2018.

the market in June 2019, resulting from the planned implementation of the MDR.<sup>29</sup> One firm, QS Zurich AG, indicated that the investment needed for recertification was “too high for a small NB.”<sup>30</sup>

The European Commission received about 47 applications from firms to be approved as NBs under the MDR by summer 2019 (in contrast to the 60 NBs currently certified for the MDD). The EU’s goal to ensure that “as many Notified Bodies as possible [are] designated prior to 2020” implies that at least some NBs may be approved after the MDR goes into effect.<sup>31</sup> The approval process for a notified body to receive EU accreditation is expected to take at least 18 months, suggesting that in order for these organizations to receive approval before the 2020 implementation date of the MDR, they would have needed to apply by the end of 2018. However, as of September 2019, only five notified bodies had been approved to serve as MDR NBs,<sup>32</sup> with the European Commission aiming for 20 certifications by the end of 2019.<sup>33</sup>

Another source of uncertainty is the fact, as noted above, that a wider array of medical devices and health services will fall under the scope of the MDR than under the MDD framework. One important and emerging field in which the MDR will likely require certification lies in the health app economy. Under the MDR, “medical device” not only applies to instruments and implants, it can also apply to software. Any software that is specifically designed for the “diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease” falls under the MDR remit. This language extends to any software that provides a potential diagnosis of disease based on a customer’s health data;<sup>34</sup> it could also extend to the use of software using artificial intelligence to diagnose disease. Health apps used in smartphones, like those related to fitness and wellness, are not regulated as medical devices.<sup>35</sup>

Finally, the MDR establishes the requirement that every medical device contain a “unique device identification” (UDI), which is “intended to improve the traceability of medical devices throughout the supply chain” by allowing data to move in real time to the new digital information repository called the European Union Database on Medical Devices (Eudamed).<sup>36</sup> This UDI change, in addition to creating a new obligation for U.S. medical device manufacturers (as well as others operating in the EU market), will create new data monitoring and processing obligations for firms. These new components may also create additional challenges for U.S.

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<sup>29</sup> Industry representative, email message to authors, October 1, 2019; Taylor, “Lloyd’s Exits Notified Body Services,” June 14, 2019.

<sup>30</sup> *Regulatory Focus*, “Another Notified Body Bows Out,” June 18, 2019.

<sup>31</sup> EC, “MDR and IVDR Implementing Measures Rolling Plan,” April 15, 2019.

<sup>32</sup> European Commission, “Notified Bodies Nando: Regulation (EU) 2017/745,” n.d. (accessed October 1, 2019).

<sup>33</sup> Arnold & Porter, “Update on the European MDR and IVDR,” June 25, 2019.

<sup>34</sup> Johner Institute, “MDR Classification Rule 11 for Medical Device Software,” n.d. (accessed October 1, 2019).

<sup>35</sup> TÜV SÜD, “TÜV SÜD Provides Information about the MDR and AI” (accessed October 1, 2019).

<sup>36</sup> Information on the Eudamed database can be accessed here: [https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/eudamed\\_en](https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/eudamed_en).

medical device manufacturers in other ways: one 2016 study concluded that approximately 15 percent of medical device recalls by the FDA during 2010–16 stemmed from labeling errors.<sup>37</sup>

## Post-Market Surveillance

Following the release of a medical device to the EU market, the MDR will require medical device manufacturers to conduct thorough post-market surveillance (PMS) and review their products for any possible indications of device malfunction. While the U.S. medical device regulatory framework as well as the EU MDD already require post-market surveillance of medical devices, the MDR extends regulatory oversight and manufacturer requirements beyond current U.S. regulation and previous EU regulation.

The MDR requires all medical device manufacturers to conduct PMS of their products, though the level of detail required varies depending on the patient risk from device malfunction. Depending on the type of medical device, a manufacturer is required to prepare either a post-market surveillance report (PMSR) or a more detailed Periodic Safety Update Report (PSUR). Table 5 provides an indication of the increasing level of detail, follow-up, and regulatory interaction required for medical device manufacturers operating in the EU market.

**Table 5:** Medical device manufacturer requirements under the MDR

Medical Classification <sup>38</sup>	PMSR or PSUR <sup>39</sup>	Submission guidelines	Frequency of updates
Class I	PMSR	Upon request	When necessary
Class IIa	PSUR	During NB conformity assessment review	Every 2 years
Class IIb (non-implantable)	PSUR	During NB conformity assessment review	Yearly
Class IIb (implantable)	PSUR	Via Eudamed for NB review	Yearly
Class III	PSUR	Via Eudamed for NB review	Yearly

Source: Oriol, “An Overview of Medical Device Periodic Safety Update Reports (PSUR),” October 2, 2018.

As indicated in the table above, the requirements and obligations for more advanced or intrusive medical devices are higher than for less advanced products. This overlaps somewhat with the approach taken by the U.S. Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act. It requires additional post-market surveillance for devices where any of the following criteria apply: failure could cause serious adverse health consequences, devices are

<sup>37</sup> Deloitte, “Preparing for the Future,” 2016.

<sup>38</sup> Further information regarding the classification of medical devices can be found in the Contemporary Regulatory Landscape section of this report.

<sup>39</sup> A Post-Market Surveillance Report (PMSR), under Article 85 of the MDR, is designed for low-risk Class I devices. It requires a summary of the conclusions of the PMS data, as well as any corrective actions for devices once they have entered the EU market. The PSUR is designed for all other types of devices. In addition to the information required in the PMSR, manufacturers are required to provide information on the current status of devices in the EU. Oriol, “An Overview of Medical Device Periodic Safety Update Reports (PSUR),” October 2, 2018.

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implanted in the patient body for more than a year, the device is necessary to sustain life, or the device has a particular impact on pediatric populations. Under the MDR, more advanced products that fall into classes II or III will be required to undergo at least yearly assessments of their products' operation in the EU market, as well as any developments that may impact the effectiveness or health outcomes of their devices (including developments that occurred outside the EU market). These new requirements for more advanced devices will also necessitate the collection of greater levels of data and increased transparency relative to U.S. regulations and previous EU regulations.

## **Recall of Devices**

Perhaps informed by the recall of faulty breast implants in the PIP controversy, the EU MDR also changes several components of the regulatory framework for the recall of faulty medical devices. While the obligations fall mostly on regulatory bodies and competent authorities, manufacturers and even distributors have obligations in the recall of medical devices.

Manufacturers who believe their devices may not be in conformity with the MDR are required to inform distributors and, when applicable, authorized representatives. Additionally, devices may also be recalled by order of competent EU regulatory authorities if the manufacturer fails to cooperate with regulatory agencies or if information is incorrect/incomplete.

For medical device distributors, many of the obligations mirror those of medical device manufacturers in terms of the recall of devices. If a distributor considers or has reason to believe a medical device does not comply with MDR standards, it is required to immediately remove the product from the market.<sup>40</sup> Distributors are also required to keep an updated register of recalls and withdrawals of medical devices, relaying information to the manufacturer and authorized representative of any changes.<sup>41</sup>

## **Impact of the MDR on EU Medical Device Market**

As with many new regulations, the transition from the old system to the new one is likely to raise costs for manufacturers and distributors. Moreover, the heightened regulatory scrutiny and likely reduction in the number of credentialed NBs may eliminate the EU's advantageous time to market for medical devices.

### **Time to Market Impact for Medical Devices May be Significant**

As discussed previously, the short time-to-market for medical devices in the EU has historically provided U.S. medical device manufacturers with a unique opportunity to offer their products to a large, mature, and economically advanced market well ahead of other major markets (including the United States). However, a number of factors within the MDR make it less likely that

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<sup>40</sup> Buttron, "EU MDR Poses Significant Changes," July 26, 2017.

<sup>41</sup> Buttron, "EU MDR Poses Significant Changes," July 26, 2017.

medical devices will be able to enter the market with the quick turnaround that historically had characterized EU market entry. This is due to the potential creation of two bottlenecks within the medical device regulatory approval supply chain: (1) manufacturers' long-term obligations complying with regulations (though the industry has indicated it is prepared to comply<sup>42</sup>); (2) shortage of NBs to approve medical devices for market distribution; and (3) government regulatory bodies will face a strain on resources and capacity.

### **Manufacturer Compliance Challenges**

Medical device manufacturers will face higher levels of regulatory scrutiny and more rigorous testing and data collection standards in bringing their devices to market, and will likely face other challenges as well. Industry associations have repeatedly expressed concerns that the July 2020 deadline for bringing the MDR into force will be too early for industry, including concerns about the absence of implementing measures and the not-yet-complete Eudamed database.<sup>43</sup> There may be substantial challenges in particular for small and medium-sized enterprises (SMEs) manufacturing medical devices for the EU market, notably if the NBs they had previously used to ensure regulatory compliance are not approved (or withdraw from the market) by the July 2020 deadline.<sup>44</sup> (Approximately 80 percent of U.S. medical device manufacturers can be classified as SMEs.)<sup>45</sup>

Additionally, the ongoing obligations for manufacturers to track medical devices already on the market (further detailed in the post-market surveillance section above) will create higher costs for the life cycle of each individual medical device, potentially limiting resources for further expansion into the creation of other devices.<sup>46</sup>

A survey from the Regulatory Affairs Professionals Society and KPMG concluded that only about one-quarter of medical device firms are prepared to fully comply with the MDR, and more than one-third of respondents indicated that they would spend more than \$5 million to become MDR compliant.<sup>47</sup> One Irish startup concurred with this assessment of costs and their impact on the wider industry, noting that “overall it will slow down the development and [number of] products coming to market in the EU, and generally people are now— particularly in startups— slower to take on the EU CE marking pathway for a truly novel innovative device than they would have been.”<sup>48</sup>

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<sup>42</sup> AdvaMed, “Subject: Urgent Action Needed,” July 17, 2019.

<sup>43</sup> AdvaMed, “Subject: Urgent Action Needed,” July 17, 2019.

<sup>44</sup> Brennan, “Notified Bodies Raise Concerns with MDR Timelines,” December 19, 2018.

<sup>45</sup> Select USA, “Industry Snapshots: Medical Device Industry,” 2018.

<sup>46</sup> MedTech Conference, “Planning for the Medical Device Market,” August 31, 2018.

<sup>47</sup> Medical Design and Outsourcing, “Report: Most Medical Device Makers Not Ready,” September 24, 2019. The survey generated responses from 230 firms, mostly in the EU and North America.

<sup>48</sup> Keane, “Medtech Firms Have a Year to Prepare,” January 13, 2019.

## **Notified Bodies Will Face Increasing Compliance Challenges, and There Will Likely be Fewer of Them**

Higher standards for NBs will make the approval process more laborious, and could lead to delays in certification, as well as a likely reduction in the number of NBs serving the market (more below). This has been noted by NBs as well as by contract development and manufacturing organizations (CDMOs), with one CDMO characterizing it thus:

With the new MDR comes also the risk of an increased workload for Notified Bodies and Competent Authorities as well as the European Commission. This means the processes for regulatory, clinical, and certification activities will take longer time. We are now planning for this to facilitate the process as much as we can. . . . *Notified Bodies are raising concerns of not being able to process all the extra work. If so, fully compliant medical devices may lose access to the European market. This is a great concern also for medical device companies and CDMOs.*<sup>49</sup>

Perhaps most importantly, representatives of the medical device field have noted that the number of certified NBs is likely to fall,<sup>50</sup> given the reduced number of applications relative to the current number of NBs. This will occur despite the *increase* in the number of products that qualify as medical devices under the MDR, which itself likely contributes to the reduction in NB applications.<sup>51</sup>

As of September 2019, only five notified bodies (the British Standards Institute, DEKRA Certification, IMQ S.p.A, TÜV Rheinland, and TÜV SÜD) had been designated by the European Commission as being fully capable of complying with the MDR and certifying medical devices.<sup>52</sup> Even if all current applications were accepted, the 47 applications would still represent an 18 percent reduction in the number of qualified MDR NBs relative to approximately 60 MDD NBs.<sup>53</sup>

The effects of the reduction in NBs are likely to be multifaceted and may exacerbate other issues within the development of the European medical device market. First, the expansion of the items that fall under the MDR will increase the strain on NBs, as more products will need MDR CE certification before entering the market. This could in turn lead to a reduction in NBs due to an inability to keep up with the more vigorous caseload required to stay competitive, which would further increase the burden on remaining NBs. According to one industry representative:

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<sup>49</sup> Bjorklund, “5 Key Aspects of the New Medical Device Regulation,” March 19, 2019.

<sup>50</sup> Rose, “Top 10 Challenges of the New MDR,” June 22, 2017.

<sup>51</sup> Rose, “Top 10 Challenges of the New MDR,” June 22, 2017.

<sup>52</sup> Oriol, “Which EU Notified Bodies Have Been ‘Designated,’” September 26, 2019.

<sup>53</sup> According to the European Commission, there are currently 59 notified bodies that are qualified to certify compliance with the Medical Device Directive.

*NBs are already facing significant capacity issues with numbers dwindling in Europe, and the more stringent requirements set out by the MDR are very likely to escalate this existing issue. NBs are in a particularly difficult Catch-22 position as there has already been a significant decrease in their numbers, but an increased demand on their services is to be expected as the MDR rolls into force.*<sup>54</sup>

Second, the NB industry may experience further consolidation, as larger companies may end up being the only ones with the legal and structural capacity to meet the ongoing requirements throughout the life cycle of a medical device in a European market.<sup>55</sup> Additionally, the “continuous life cycle” component of the MDR regulatory framework may have long-term effects on the NB industry for medical devices. As each device will need to be tracked with UDIs throughout the life cycle, and as regulatory requirements following market introduction have been strengthened, it may be difficult for new providers to enter the market, given the much longer time horizon for the tracking and monitoring of new medical devices.

Finally, industry representatives have noted the potential for “growing pains” among NBs in the early stages of MDR enforcement. However, once those hurdles are overcome, these NBs will be far better placed than firms that enter later in the process and experience their own “growing pains.”

### **Government Regulatory Bodies Will Also Face Strains on Resources and Capacity**

Higher standards and new layers of regulatory oversight will add strain to the capacity of competent authorities, creating the potential for delays throughout the regulatory approval, market surveillance, and recall stages of the medical device life cycle. One industry assessment highlighted the heavier demands on these authorities, both from the increase in the number of medical devices and the expanded definition of a medical device. These new demands have increased the strain on government regulatory bodies, which are “desperately looking for qualified staff to implement the new regulations.”<sup>56</sup>

## **Conclusion**

The United States has long been the world’s leading medtech industry, with the EU serving as its principal market. The size of the EU market, coupled with its relatively low time to market, have made the trading bloc an especially attractive destination for U.S. medtech exports. However, the

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<sup>54</sup> Rose, “Top 10 Challenges of the New MDR,” June 22, 2017.

<sup>55</sup> The concern over increased regulatory burdens indirectly contributing to the consolidation of industry is not limited to the regulation of medical devices. Several industry experts in the online advertising space posited that the introduction of the European Union’s General Data Protection Regulation (GDPR), which regulates the personal data of European data subjects, would actually lead to a consolidation of the online advertising industry, as smaller firms would be unable to comply with the new regulatory requirements of GDPR. Hemann, “Digital Advertising and GDPR: A Growth (and Consolidation) Story,” December 5, 2018.

<sup>56</sup> Dinkoh, “Implementing MDR Is Complex and Expensive,” March 5, 2018.

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EU's implementation of the MDR may jeopardize the region's reputation for timely market approvals. The MDR's expansive regulatory scope, coupled with the apparent shortage of NBs to process applications, suggests the possibility of significant delays. It remains to be seen how the new policy impacts investment and trade decisions by U.S. firms, but initial evidence suggests that they could be adversely affected by longer wait times to introduce medical devices, potentially slowing innovative potential for U.S. firms operating in the European market.

Additionally, the MDR's changes to the requirements surrounding clinical trials, the gathering of research data for medical devices, post-market surveillance of devices, and the recall of medical devices has the potential to increase administrative and monitoring costs for firms. Labeling requirements and ongoing database management will also create new challenges for U.S. medical device firms as they navigate an increasingly complex regulatory framework in their largest market.

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