

# What to Expect from New EU Medical Device Regulations

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**New medical device regulations in Europe will be finalized this year or next. Here's what manufacturers can expect.**



Every time there is a major public health scandal, governments respond with “new and improved” regulations. Such has been the case in the wake of the Poly Implant Prothèse breast implant scandal, in which the French manufacturer substituted approved medical-grade silicone with industrial-grade silicone that resulted in rupture of the implants and systemic health problems, including death.

In September 2012, the European Commission released a [proposal](#) for new European medical device regulations (EMDR) intended to prevent similar events from occurring in the future. The final regulations were expected to be published this year but may take until 2015.

The new EMDR will be the most sweeping changes to medical device regulation in Europe since the 1990s, and industry experts are concerned that the new regulations will increase costs and eliminate the early access to device innovations that patients in Europe currently experience when compared with the rest of the world.

## **Expected Changes**

Since their release, the proposed regulations have become a [bureaucratic Frankenstein](#), with many deviations from the original proposal. The following are the most significant changes:

- The European Commission will be able to review recommendations for CE Marking prior to approval (i.e., the scrutiny process).
- The European Commission's ability to create common technical specifications (CTS) will be expanded to all devices.
- Only newly created Special Notified Bodies will be able to issue CE Certificates for high-risk devices such as implants.
- Notified Bodies will be audited for compliance with the new regulations jointly by Competent Authorities (i.e., the regulatory body for each member state). Until 2013, audits of Notified Bodies were performed only by the Competent Authority from the member state in which the Notified Body is located.
- Manufacturers will be subject to unannounced audits by Notified Bodies.
- Spinal implants, devices that control and monitor active implants, nanomaterials, aphoresis machines, and combination products will be reclassified as Class III devices requiring technical documentation known as a design dossier.
- Most in vitro diagnostics (IVDs) will require Notified Body involvement.
- A Unique Device Identification (UDI) system will be required for labeling, and the European Databank on Medical Devices (Eudamed) will be expanded.
- Formatting of declarations of conformity and technical files will be revised.

### **Potential Impact on Manufacturers**

The most concerning change to European medical device regulations for manufacturers is the addition of Article 44, a [scrutiny process](#) allowing authorities to take a second look at the Notified Body's review of technical documentation prior to CE marking approval. The scrutiny process will require Notified Bodies to prepare a summary report of the technical review for an oversight group prior to approving CE Marking of high-risk devices. The oversight group may request additional information and testing results, potentially delaying the submission process by several months and thus reducing the market advantage of launching products in Europe first.

The ability for the EU Commission to create a new CTS when an international standard does not exist could be helpful, but the commission might also replace international standards it does not agree with. International standards are developed with input from industry, but the commission could impose stricter requirements without input from industry.

The review of Notified Bodies has already begun due to fraudulent activities by some Notified Bodies and inconsistent interpretation of the Medical Devices Directives (MDD). Joint audits of Notified Bodies by two Competent Authorities simultaneously are forcing both Notified Bodies and Competent Authorities to resolve differences in the interpretation and enforcement of the three directives.

These joint audits have already resulted in the closure of two noncompliant Notified Bodies. Further attrition may occur if Notified Bodies are unable to qualify as Special Notified Bodies for high-risk devices. This will reduce revenues for Notified Bodies and force smaller Notified Bodies to merge or go out of business. Consolidation of Notified Bodies will also force many

manufacturers to transfer from their current Notified Body to one of the few Special Notified Bodies that can issue CE Certificates for high-risk devices.

[Unannounced audits](#) by Notified Bodies are underway, but there have been few such audits because the Notified Bodies are still in the planning stages. Most of the unannounced audits for 2014 are expected to take place during the second half of the year. The increased workload created by unannounced audits will mean higher revenues for Notified Bodies and higher costs for manufacturers, but there is also evidence of aggressive auditor recruiting by all the Notified Bodies, and auditor turnover is high. In the past, manufacturers benefited from having the same auditor for years, but turnover is resulting in Notified Bodies assigning a new auditor almost every year.

IVD manufacturers will experience the most significant changes under the new EMDR. Currently, only one in five IVD products require Notified Body involvement, but expected changes will require 80% of these products to have Notified Body involvement.

MDD-regulated devices will also see changes in Notified Body involvement. Several devices will be [reclassified](#) to Class III and require a design examination certificate. These product-specific CE Certificates require review and approval of all design changes, whereas under the current system, only significant changes require review and approval.

Manufacturers will also be required to update the format of technical files, declarations of conformity, and labeling. The new format requires manufacturers to create a summary document for each section instead of providing complete protocols and reports.

Currently, there is only vague guidance for the format and content of a declaration of conformity, but the proposed regulations include a prescriptive outline for format and content. The new format must also include a [UDI](#), requiring labeling for all device classifications to be changed. In addition, manufacturers will be required to more clearly disclose any residual risks associated with a device. This additional information will be included as warnings and precautions in the instructions for use and will be submitted to Eudamed.

### **When Will Changes Be Finalized?**

The final version of the EMDR is expected to be approved in late 2014 or early 2015. However, a more likely estimate is October 2015.

A September 2013 [survey](#) by the trade group Eucomed pegged the cost of the proposed regulations at €17.5 billion (\$24.3 billion). With the EU in the middle of a financial crisis, political pressures could force the European Council and Parliament to make major revisions to the proposed regulations to reduce the cost of implementation.

Some key elements must also be in place before implementation of the EMDR can begin. First, Notified Bodies need more staff—especially for high-risk devices. Second, [Eudamed](#) must be ready to implement UDI labeling and other new documentation required. Third, the European Commission plans to build a new centralized organization to oversee the Notified Bodies. Each of these elements will take more than a year to implement, and planning has just begun.

The original September 2012 proposal indicated that there would be a three-year transition period (from 2014 to 2017) for implementation of the new regulations. The transition would

begin with the highest-risk Class III devices, and lower-risk devices would be phased in over the three years. However, if the EMDR are finalized in October 2015, the implementation period will end in late 2018.

### **Will the New Regulations Be an Improvement?**

Stricter regulation of Notified Bodies and conversion of the three directives to two device regulations should reduce inconsistencies between Notified Bodies. However, the CE Marking process could also become more expensive and slower. UDI implementation and expansion of the Eudamed database will improve device safety, but unannounced audits and the scrutiny process will only increase costs for manufacturers. Overall, the new regulations are likely to result in much higher costs with minimal benefit for manufacturers.

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