



Classification changes



Background to changes

Since the European Union began regulating medical devices in the 1990s, a key element of the regulatory system has been the risk classification system based on risks related to invasiveness, anatomical location, and duration of contact. Its purpose was to ensure that devices would be regulated in a proportionate manner, whilst maintaining a high level of protection of health. The aim was also to minimize any bureaucratic burden imposed on manufacturers. In particular, a rule-based system was devised to allow manufacturers themselves to identify the applicable risk class without having to apply for it.

In 2012 the European Commission proposed a new Regulation on Medical Devices (commonly referred to as the Medical Device Regulation or MDR). The proposal was adopted in the second quarter of 2017. Despite the substantial changes to the current regulatory system contained in the original proposal and its subsequent amendments, the classification system remains substantially intact. The main changes result from technological developments and experience gained with some device categories in terms of better awareness of risks.

- a) there are some new implicit risk classifications based on conformity assessment requirements, including Class III custom implants, Class III implants, Class IIb implants, Class IIb active devices intended to administer or remove a medicinal substance and Class I_r;
- b) many devices have been upclassified based on a reassessment of risk;
- c) many devices have been upclassified or will be subject to conformity assessment under the MDR for the first time, due to new risk categories such as incorporating human-derived tissues rendered non-viable and nanomaterials likely to act.



Actions

Immediate actions — you should carry out the following actions as soon as possible:

- ✔ Identify which of your products could move to a different risk class (in most cases in a higher risk class);
- ✔ Identify the new compliance requirements resulting from reclassification; and
- ✔ Develop an action plan to deal with the new compliance requirements.

At the latest when your notified body is designated under the MDR:

- ✔ Ensure that you have a common understanding between you and your notified body on any issues of interpretation regarding classification and the relevant compliance requirements; and
- ✔ Come to an agreement with your notified body on an implementation timeline.

You should understand that there may be fewer notified bodies under the MDR than there are currently under the Medical Devices Directives (MDD) (93/42/EEC). Because of the possibility that timely access to the assessment and certification by notified bodies will become a scarcer resource, it is important to act as soon as it becomes possible to achieve compliance under the MDR.

Get in Touch

Smart Support is designed to outline the impact of the new regulatory changes, in order for your business to prepare to navigate the transition and implement the new requirements.

Each Smart Support topic is written by an industry expert and reviewed by a topic expert and advisory panel, providing you with:

- ✓ An executive summary suitable for senior management
- ✓ Detailed practical guidance on what has changed and what this means for your organization
- ✓ Actions to take now and a summary of what is still to change

To access the full text of the MDR/IVDR Smart Support and find out more about Compliance Navigator, contact us today.

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