Authorized representatives
Background to changes

The EU Medical Devices Regulation 2017/745 (MDR) has significantly increased the burden of compliance and potential legal liability exposure for economic operators, including EU authorized representatives (ARs) of manufacturers established outside of the European Economic Area (EEA), Switzerland and Turkey. Whereas the main focus of the EU Medical Devices Directive 93/42/EEC (MDD) was the manufacturer of a medical device, the MDR explicitly identifies a pivotal role for ARs in ensuring the compliance of the medical devices produced by manufacturers established outside the EU as well as serving as their contact persons within the EU.

The MDR details a minimum mandate for ARs, requires them to each appoint at least one person responsible for regulatory compliance (PRRC) and requires them to register in the European database (Eudamed). For enforcement purposes, the MDR also makes ARs legally liable on the same basis as (and jointly and severally with) manufacturers for defective medical devices in cases where a manufacturer has not complied with its own general obligations.

The AR’s increased compliance responsibility is part of the MDR’s overall objectives, which include establishing a safer and more transparent legislative framework for medical devices and the restoration of confidence in the ability of the legislation to provide a high level of health protection. The MDR aims to make the application of medical device compliance requirements across the EEA, Switzerland and Turkey more uniform because it is directly applicable legislation and is intended to help reduce divergent interpretation and practice across the member states. Member state laws will still remain of importance though – for example, for enforcement.

ARs must be meeting all their obligations under the MDR in order for the manufacturers that they represent to be certified as MDR compliant, unless there are obligations which are explicitly deferred, such as AR registration for class I and custom made medical devices, where MDD registration rules will remain applicable for a specified period.
Actions

All the above points mean that ARs and manufacturers need to:

✅ Review their existing processes and personnel resources to implement the changes and then sustain compliance.

✅ Identify who will be the AR's PRRC(s) early in this process and work closely with them in effecting the adjustments needed for MDR compliance.

✅ Update the AR contract to meet MDR requirements and be prepared to give special consideration to the level of liability protection the AR may require. Existing mandates will also have to be updated so manufacturers will need to engage with their existing ARs to do this.

✅ Develop an effective implementation plan for the changes that is integrated with their overall programmes to move to compliance with all the aspects of the MDR, including member state laws which will continue to govern enforcement and liability.
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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