MDR and IVDR FAQs Series

Responsible persons, authorized representatives and the new EU Regulations

bsi. Compliance Navigator
for Medical Devices

Responsible persons under the MDR and IVDR

What are some of the key areas of responsibility for persons responsible for regulatory compliance under the MDR and IVDR?

Manufacturers and authorized representatives (ARs) for both medical devices and in vitro diagnostic devices (IVDs) must appoint at least one person responsible for regulatory compliance with responsibilities that cover the quality management system (QMS), regulatory documentation, post-market surveillance and vigilance reporting, and devices used for clinical investigation.

Can the responsibilities of this role be shared?

The responsibilities can be divided between more than one person provided that the responsibility of each individual is defined in writing and all responsibilities are covered.

Does the person responsible for regulatory compliance need to be an employee of the manufacturer?

For the manufacturer, the person(s) responsible for regulatory compliance has to be available within their organization, i.e. is an employee of the manufacturer, unless they meet the definition of a small manufacturer.

Small manufacturers do not have to have the person responsible for regulatory compliance within their organization but they have to be permanently and continuously available to them. Similarly, the person responsible for regulatory compliance in the AR does not have to be within their organization but has to be permanently and continuously available.

Are 'management representatives' in the context of ISO 13485 the same as persons responsible for regulatory compliance?

BS EN ISO 13485:2016, the standard for a QMS for medical device organizations, has a requirement to appoint a management representative; it should be noted that the responsibilities of the management representative and the person responsible for regulatory compliance are not the same. Whilst there are some aspects of the responsibilities of the person responsible for regulatory compliance that are complementary to those of the management representative, and might be allocated as additional responsibilities of that individual, all the requirements for the management representative and the person responsible for regulatory compliance need to be documented within the QMS.

How do the requirements for persons responsible for regulatory compliance differ between the MDR and the IVDR?

In many aspects, the requirements of the IVDR parallel the MDR; in regards to the requirements for the person responsible for regulatory compliance, the requirements are identical except that for medical devices the experience requirements apply to experience with medical devices and for IVDs the experience requirements apply to experience with IVDs.

Authorized representatives under the MDR

How does the MDR affect the responsibilities and liabilities of authorized representatives?

The 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 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.

What are some of the key implications of the MDR for ARs?

The MDR details a minimum mandate for ARs, requires them to each appoint at least one person responsible for regulatory compliance 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.

What are the reasons behind this regulatory change?

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.

Can a manufacturer be certified as MDR compliant even if its AR is not complying with the Regulation?

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.

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