



Responsible persons

The role of the person responsible for regulatory compliance



Background to changes

The 2017 Medical Devices Regulation (MDR) (Regulation (EU) 2017/745) and In Vitro Diagnostic Regulation (IVDR) (Regulation (EU) 2017/746) are significant changes to European legislation for medical devices and in vitro diagnostic medical devices (IVDs). Understanding the requirements is essential to your ability to provide the European Union market with safe medical devices that perform as intended and comply with the Regulations. One significant new requirement is that manufacturers and authorized representatives for both medical devices and IVDs appoint at least one person responsible for regulatory compliance with responsibilities that cover the quality management system (QMS), regulatory documentation, postmarket surveillance and vigilance reporting, and devices used for clinical investigation.

This person responsible for regulatory compliance has to:

- ✓ meet designated minimum requirements for qualification and experience; and
- ✓ discharge defined responsibilities.

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.

The name, work address and contact details of the person or persons responsible for regulatory compliance have to be included in the information provided with the registration of the manufacturer or authorized representative and kept up to date thereafter when changes are made.



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 authorized representative does not have to be within their organization but has to be permanently and continuously available.

The person responsible for regulatory compliance should not be financially or professionally disadvantaged for properly fulfilling their duties, whether or not they are employees of the organization or are contracted to it.

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 requirement 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.



The Regulations were published in the Official Journal (OJ) of the European Union on 5 May 2017 and their entry into force is 20 days after publication. With publication in the OJ, the Regulations entered into force on 26 May 2017. The transition period for the MDR is three years and so the transition period of the MDR ends on the date of application, that is, 26 May 2020. For the IVDR, the transition period is five years and so the date of application for the IVDR, and the end of its transition period, is 26 May 2022.

The current Medical Devices Directives (MDD) (93/42/EEC) and In Vitro Diagnostic Medical Devices Directive (IVDD) (98/79/EC) are repealed on the date of application of the MDR and IVDR (26 May 2020 and 26 May 2022 respectively), unless any provisions are specifically identified otherwise in the Transitional Provisions. There are no specific additional transitional arrangements regarding the person(s) responsible for regulatory compliance and so the requirements for the person responsible for regulatory compliance apply to:

- ✓ manufacturers and authorized representatives of devices from the date that their first device is CE marked under the MDR or IVDR, whether applied during the transition period or after the entry into force; and
- ✓ manufacturers and authorized representatives of any devices CE marked and legally marketed under valid certificates issued for the MDD or IVDD from the date of application of the Regulations.

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 in vitro diagnostic devices (IVDs) the experience requirements apply to experience with IVDs. This guidance is intended to apply to both Regulations unless specifically indicated as applicable to medical devices or IVDs.

Actions

You will need to:

- ✓ analyse where the defined responsibilities for the person responsible for regulatory compliance lie in your organization;
- ✓ define the position(s) that will be nominated with responsibility as the person(s) responsible for regulatory compliance;
- ✓ identify the individual in the position(s) and confirm that they meet the qualification, experience and availability requirements;
- ✓ provide training or take other action if the qualification or experience requirements are not met;
- ✓ review the processes within the QMS that drive meeting the requirements under the responsibility of the person responsible for regulatory compliance;
- ✓ confirm that these processes allow the person(s) responsible for regulatory compliance to fulfil their responsibilities or are adjusted so that they do;
- ✓ establish the means to include the details of the person responsible for regulatory compliance in the registration of the manufacturer or authorized representative in the Eudamed database and keep this information up to date.

All the above points mean that you need to review your existing processes and look at resource needs to implement the changes and then sustain compliance. You need to develop an effective implementation plan for these changes that are integrated within your overall programme to move to compliance with all the aspects of the Regulations.

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.

T: +44 (0)20 8996 7029
E: cservices@bsigroup.com
bsigroup.com/complonav