EU Medical Device Regulation — MDR

Important points for manufacturers

Manufacturers intending to place medical devices on the EU market should carefully assess the applicable MDR requirements at an early stage of the certification process.

In particular, manufacturers should:

- confirm whether their product qualifies as a medical device under the MDR;
- determine the correct risk class of the device;
- assess whether the product falls within Annex XVI of the MDR, even if it does not have an intended medical purpose;
- perform a gap analysis against the applicable MDR requirements;
- integrate the applicable MDR requirements into their quality management system;
- demonstrate conformity with the General Safety and Performance Requirements set out in Annex I of the MDR;
- prepare and maintain technical documentation in accordance with Annexes II and III of the MDR;
- determine whether the involvement of a Notified Body is required;
- select a Notified Body designated under the MDR for the relevant device type and conformity assessment scope.

The involvement of a Notified Body is required for class IIa, IIb and III medical devices, as well as for certain class I devices, including devices placed on the market in sterile condition, devices with a measuring function and reusable surgical instruments.

Manufacturers should also take into account that conformity assessment activities may require sufficient time, particularly where specific consultation procedures, additional regulatory assessments or complex technical and clinical evaluations are applicable.