Classification and Conformity Assessment

Under the EU's MDR, the device manufacturer determines the regulatory class of the device and picks the conformity assessment path. Depending on the device classification, there may also be Notified Body involvement.

In addition, the Active Implantable Medical Device directive will be retired, so those devices now fall under the MDR and its classification rules.

Classification Rules
Following Article 51, the device classes are I, IIa, IIb, and III, which take into account the intended purpose and the inherent risk. Annex VIII has the rules for device classification.

Annex VIII starts with defined terms related to duration of use, invasive devices, and active devices.

There are 22 rules divided into non-invasive devices, invasive devices, active devices, and special rules.

Apply the rules based on the intended purpose of the device.

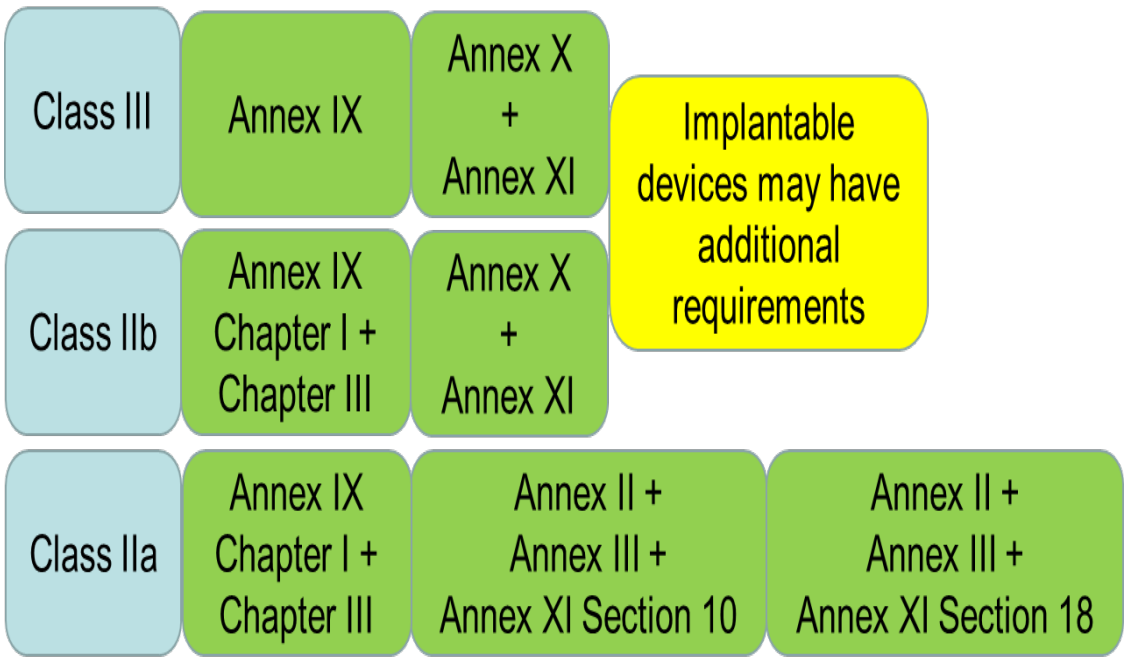
For a device intended for use with another device, classify each device separately. Classify accessories in their own right, separately from the parent device.

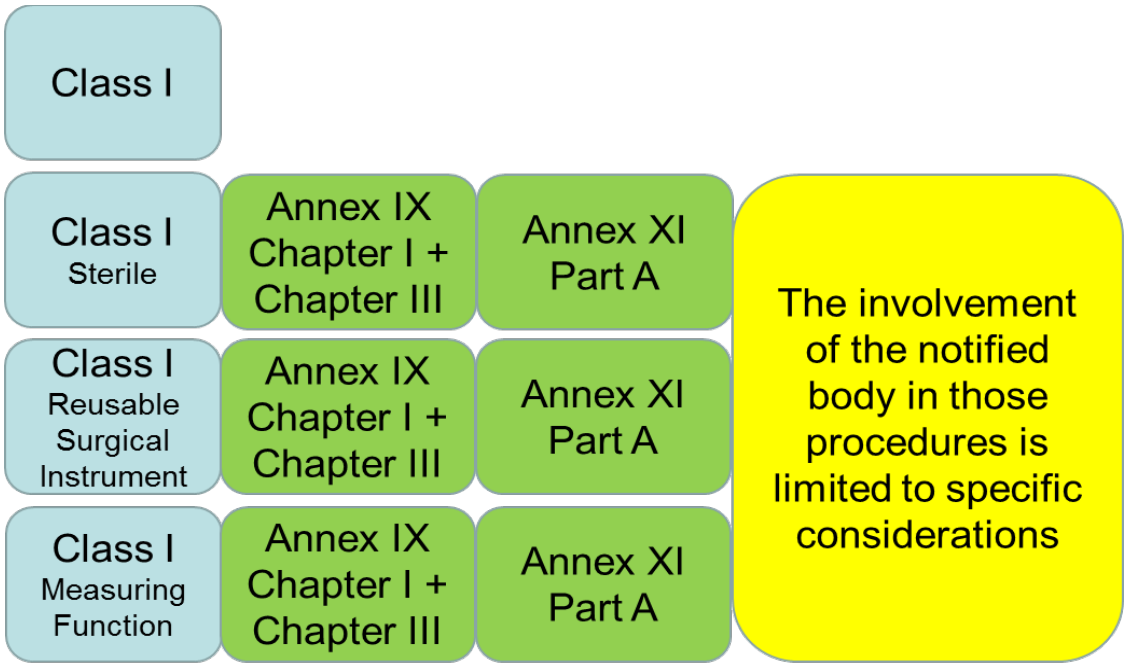
Start with Rule 1 and go through each rule in order. If the rule applies, it determines a risk class, I, IIa, IIb, or III. In the event the rules provide more than one risk class, classify the device into the highest risk class.

Conformity Assessment
Conformity Assessment means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled

CE Marking of Conformity or *CE Marking* means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonization legislation providing for its affixing

Article 52 provides the conformity assessment procedures using the device class and various annexes that lead to CE Marking. The diagram below illustrate the conformity assessment paths.


Class III
Annex IX
Annex X + Annex XI
Implantable devices may have additional requirements
Class IIb
Annex IX Chapter I + Chapter III
Annex X + Annex XI
Class IIa
Annex IX Chapter I + Chapter III
Annex II + Annex III + Annex XI Section 10
Annex II + Annex III + Annex XI Section 18


Class I
Class I Sterile
Annex IX Chapter I + Chapter III
Annex XI Part A
The involvement of the notified body in those procedures is limited to specific considerations
Class I Reusable Surgical Instrument
Annex IX Chapter I + Chapter III
Annex XI Part A
Class I Measuring Function
Annex IX Chapter I + Chapter III
Annex XI Part A