UDI IN THE EU MDR

BEFORE placing a device on the market:

Assign the Basic UDI-DI & submit to Eudamed along with the core data elements

Direct Marking (reusable devices)

26 May 2021	26 May 2023	26 May 2025	26 May 2027
Implantable & Class III	Class IIa & Class IIb	Class I	

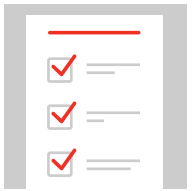
Labels & Packaging

Regulations

are legal requirements written at a high level and do not state necessarily how to do something, but state typically what must be achieved

- *Outcome rather than instruction*

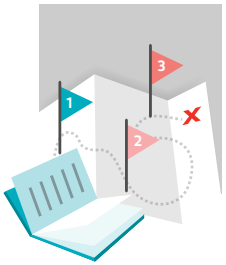
Standards



are much more prescriptive; as well as giving requirements, they give much more detail on how to do something

- *Detail of requirements to achieve desired quality outcome*

Guidance documents



provide more of a 'cookbook' approach and go into specifics

- *Step-by-step information for meeting the requirements*

bsi. Compliance Navigator for Medical Devices

EU MDR Articles Related to UDI

- 27 Unique Device Identification [UDI] system
- 28 UDI database
- 29 Registration of devices
- 31 Registration of manufacturers, authorized representatives and importers
- 32 Summary of safety and clinical performance
- 60 Certificate of free sale

EU MDR Annexes Related to UDI

II	Technical documentation
IV	EU declaration of conformity
VI, part A	Information to be submitted upon registration of devices and economic operators
VI, part B	Core data elements to be provided to the UDI database together with the UDI-DI [in accordance with Articles 29(4) and 31]
XII	Certificates issued by a notified body [in accordance with Articles 28 and 29]

Article 27

Unique Device Identification System

1. States the requirement for implementing a UDI system
2. Specifies need to designate one or multiple 'issuing entities' to assign UDI
3. Manufacturer must assign a UDI to the device and all higher levels of packaging before placing the device on the market
4. UDI carriers shall be placed on the label of the device and on all higher levels of packaging
5. UDI must be used for reporting serious incidents and field safety corrective actions
6. Basic UDI-DI must appear on the EU declaration of conformity
7. Manufacturer must keep a current list of all assigned UDIs in the technical documentation

bsi. Compliance Navigator for Medical Devices