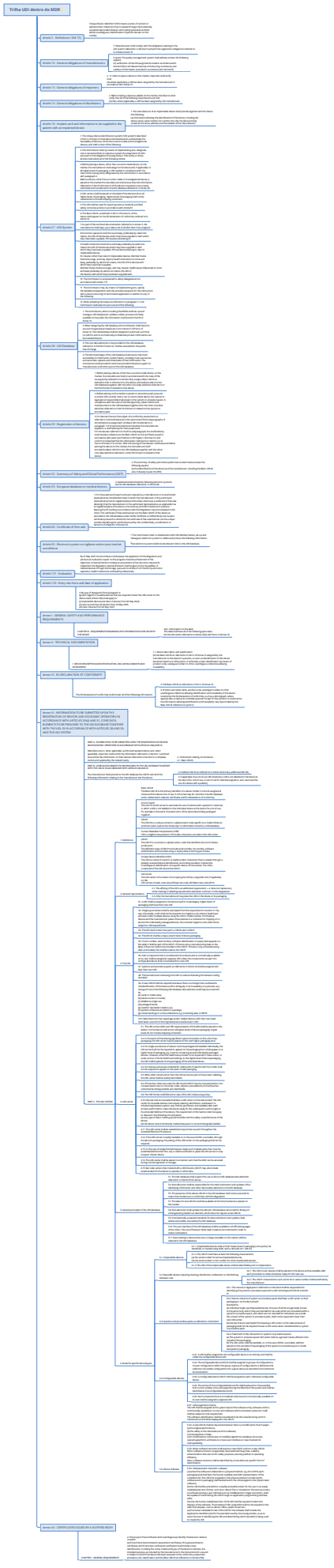
Trilha do UDI dentro do MDR


Trilha UDI dentro do MDR
Article 2 - Definitions (Ref 70)
Article 10 - General obligations of manufacturers
Article 13 - General obligations of importers
Article 14 - General obligations of distributors
Article 19 - Implant card and information to be supplied to the patient with an implantable device
Article 27 - UDI System
Article 28 - UDI Database
Article 29 - Registration of devices
Article 52 - Summary of Safety and Clinical Performance (SSCP)
Article 53 - European database on medical devices
Article 60 - Certificate of free sale
Article 92 - Electronic system on vigilance and on post-market surveillance
Article 121 - Evaluation
Article 123 - Entry into force and date of application
Annex I - GENERAL SAFETY AND PERFORMANCE REQUIREMENTS
Annex II - TECHNICAL DOCUMENTATION
Annex IV - EU DECLARATION OF CONFORMITY
Annex VI - INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS ON THE UNIQUE DEVICE IDENTIFICATION DATABASE AND ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI, IN ACCORDANCE WITH ARTICLES 28 AND 29, AND THE UDI CENTRE
Part A - Information to be submitted to the UDI database and at the following information relating to the device and the device
1. Information relating to the device
1.1. Basic UDI-DI.
1.2. If applicable, the prefix of the UDI-DI assigned to the device
1.3. If applicable, the name of the system or procedure pack
1.4. Trade name or trade name(s) (if different from the one in the device nomenclature)
1.5. Intended use (e.g. diagnosis and treatment, pre-operative, surgical, post-operative care, monitoring, diagnostic, prognostic, therapeutic, rehabilitation, life support, life sustaining, disinfection, sterilisation, contraception, assisted reproduction, aesthetic, aesthetic and cosmetic, disease management, and / or monitoring, replacement or support of anatomy, physiology, or a pathological condition, or a combination of the above)
1.6. Intended medical specialty
1.7. Intended patient population
1.8. Intended user(s)
1.9. Device model, version, serial number, software identification or other identifiers
1.10. Device description (including, where applicable, a description of the device including its components, accessories, software, and a description of the raw materials used in products which are intended to come into contact with the patient or user)
1.11. Sterile / non-sterile
1.12. Reusable / single use
1.13. Implantable device
1.14. Reusable devices requiring cleaning, disinfection, sterilisation or refurbishing before use
1.15. Systems and procedure packs as referred to in Article 22
1.16. Device for specific investigations
1.17. Device for specific development purposes
1.18. Configurable devices
1.19. Medical devices
1.20. Medical devices containing medicinal substances
1.21. Medical devices containing human blood or blood products
1.22. Medical devices containing human tissues or cells, or their derivatives
1.23. Medical devices containing tissues or cells of animal origin, or their derivatives
1.24. Medical devices manufactured utilising tissues or cells of animal origin
1.25. Medical devices manufactured utilising human tissues or cells
1.26. Medical devices manufactured utilising human blood or blood products
1.27. Medical devices manufactured utilising human blood or blood products
1.28. Medical devices manufactured utilising human blood or blood products
1.29. Medical devices manufactured utilising human blood or blood products