MDR readiness checklist

This checklist allows you to determine if your quality management system and technical documentation are meeting the Medical Device Regulation (MDR) requirements, and highlight the areas where your business activities may already comply.

Working through the checklist will provide an overview of the additional work you may need to carry out before your initial MDR conformity assessment.

Please note that the checklist cannot count as evidence for your transition audit, as our auditors will have to confirm compliance with the standard during your initial MDR conformity assessment.

SCOPE, CLASSIFICATION AND ROUTES OF CONFORMITY

The Regulation scope has significantly increased, and some devices may have classification and conformity route changes.

HAVE YOU:	READY	NEARLY READY	WORK TO DO
Have you identified the impact of the new MDR classification on the conformity assessment that should be carried out for each device in your scope, as per Annex VIII?			

TRANSITIONAL PROVISIONS

A device with a valid Medical Device Directive (MDD) certificate can continue to be placed on the market until the certificate expires and if no significant changes in the design and intended purpose are made. However, the below Regulation requirements shall be in place with immediate effect after May 25, 2021, (Article 120 – Point 3) and will be part of your next surveillance under MDD.

HAVE YOU IMPLEMENTED:	READY	NEARLY READY	WORK TO DO
Post-market surveillance?			
Market surveillance?			
Vigilance?			
Registration of economic operators?			

GENERAL REQUIREMENTS

HAVE YOU:	READY	NEARLY READY	WORK TO DO
Have you implemented a system to identify new devices added to the scope or reclassified devices, according to the classification routes?			
Based on the classifications, have you identified and followed an appropriate conformity assessment procedure (MDR Article 52)?			
Have you created a single registration number (SRN – Article 31)?			
Have you registered an economic operator (Article 30)?			
Have you considered the increased obligations and agreements with importers and distributors (Articles 13, 14 and 16)?			
Have you nominated a person responsible for regulatory compliance (Article 15)?			

HAVE YOU:	READY	NEARLY READY	WORK TO DO
Have you worked on an agreement with an EU-authorized representative (Article 11)?			
Have you set a strategy for regulatory compliance, unique device identification and registration, and handling communication with authorities, notified bodies and economic operators?			
Have you defined a process for producing, monitoring and controlling the UDI system (UDI-DIs and UDI-PIs) and how to place it on the device (Article 27-29)?			
Have you updated your declaration of conformity?			
Have you assessed the impact of MDR on your labeling and new requirements, such as the implant card (Article 18)?			

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

HAVE YOU:	READY	NEARLY READY	WORK TO DO
Have you considered that the MDD essential requirements have been replaced by the general safety and performance requirements? Have you ensured compliance with all the new GSPRs?			

TECHNICAL DOCUMENTATION

HAVE YOU:	READY	NEARLY READY	WORK TO DO
Have you ensured that the technical documentation is in English and an organized, readily searchable and unambiguous manner?			
Have you updated your technical documentation, in accordance with Annex II and III of MDR?			
Have you considered the life-cycle approach?			
Have you included the new requirements, such as UDI, state-of-the-art, clinical evaluation requirements, summary of safety and clinical performance, periodic safety update report and new Italian nomenclature for each of the technical documents?			
Have you considered the summary of safety and clinical performance (Article 32), if applicable?			

POST-MARKET

HAVE YOU IMPLEMENTED PROCEDURES FOR:	READY	NEARLY READY	WORK TO DO
An adequate pro-active gathering of data before applying for MDR certification?			
PMS Plan – Article 84?			
PMS Report – Article 85?			
Periodic Safety Update Reports – Article 86?			
Reporting serious incidents and field safety corrective action – Article 87?			

CLINICAL EVALUATION

HAVE YOU:	READY	NEARLY READY	WORK TO DO
Have you gathered sufficient clinical evidence for your device?			
For all Class III implantable devices and Class IIb active devices that administer or remove a medicinal product, have you considered whether your device will need or can be exempt from clinical evaluation consultation procedure (Article 54)?			
Have you managed to comply with MDR's new equivalence route requirement, and evaluated the necessity of clinical investigation or justification if not relevant?			

EUDAMED

HAVE YOU:	READY	NEARLY READY	WORK TO DO
Have you started registering your device in EUDAMED (Article 29)?			
Have you prepared a process and procedure to interact with EUDAMED?			

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