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MDR – Compliance Checklist

Manufacturer

MDR Article	MDR Requirement	Compliance Status	Comment
Article 10 (1)	When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.	To be done	When all processes and documents as mentioned in the requirements below are available and used, this shall be compliant.
Article 10 (2)	Manufacturers shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I.	To be done	Have a risk management process and documents for all custom-made devices and patient solutions. Using the supplied process can secure compliance.
Article10 (3)	Manufacturers shall conduct a clinical evaluation in accordance with the requirements set out in Article 61 and Annex XIV, including a PMCF.	To be done	Have a clinical evaluation process and documents for all custom-made devices and patient solutions. Using the supplied process can secure compliance.
Article 10 (16)	Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law. Manufacturers shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.	To be done	An ensurance for damage compensation needs to be in place to achieve compliance.
Article 15 (1)	Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices. The requisite expertise shall be demonstrated by either of the following qualifications: (a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices; (b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices. Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate the requisite expertise referred to in the first subparagraph by having at least two years of professional experience within a relevant field of manufacturing.	To be done	If a person responsible for regulatory compliance is assigned this requirement is fulfilled.