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MDR – Compliance Checklist

Manufacturer of custom-made medical devices

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.
Annex XIII (1)	For custom-made devices, the manufacturer or its authorised representative shall draw up a statement containing all of the following information:	To be done	If the patient solution statement (template provided by Ottobock) is used, this requirement is fulfilled.
Annex XIII (1)	— the name and address of the manufacturer, and of all manufacturing sites,	To be done	If the patient solution statement (template provided by Ottobock) is used, this requirement is fulfilled.
Annex XIII (1)	— if applicable, the name and address of the authorised representative,	To be done	If the patient solution statement (template provided by Ottobock) is used, this requirement is fulfilled.
Annex XIII (1)	— data allowing identification of the device in question,	To be done	If the patient solution statement (template provided by Ottobock) is used, this requirement is fulfilled.
Annex XIII (1)	— a statement that the device is intended for exclusive use by a particular patient or user, identified by name, an acronym or a numerical code,	To be done	If the patient solution statement (template provided by Ottobock) is used, this requirement is fulfilled.
Annex XIII (1)	— the name of the person who made out the prescription and who is authorised by national law by virtue of their professional qualifications to do so, and, where applicable, the name of the health institution concerned,	To be done	If the patient solution statement (template provided by Ottobock) is used, this requirement is fulfilled.
Annex XIII (1)	— the specific characteristics of the product as indicated by the prescription,	To be done	If the patient solution statement (template provided by Ottobock) is used, this requirement is fulfilled.
Annex XIII (1)	— a statement that the device in question conforms to the general safety and performance requirements set out in Annex I and, where applicable, indicating which general safety and performance requirements have not been fully met, together with the grounds,	To be done	If the patient solution statement (template provided by Ottobock) is used, this requirement is fulfilled.

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Annex XIII (1)	— where applicable, an indication that the device contains or incorporates a medicinal substance, including a human blood or plasma derivative, or tissues or cells of human origin, or of animal origin as referred to in Regulation (EU) No 722/2012.	To be done	If the patient solution statement (template provided by Ottobock) is used, this requirement is fulfilled. This most likely is only applicable for materials of animal origin (e.g. leather)
Annex XIII (2)	The manufacturer shall undertake to keep available for the competent national authorities documentation that indicates its manufacturing site or sites and allows an understanding to be formed of the design, manufacture and performance of the device, including the expected performance, so as to allow assessment of conformity with the requirements of this Regulation.	To be done	Control and document your manufacturing processes
Annex XIII (3)	The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces devices which are manufactured in accordance with the documentation referred to in Section 2.	To be done	Control and document your manufacturing processes. At minimum a control of the manufacturing specification should be performed, e.g. record fitting or measurements of geometrical specifications delivered by the PCC.
Annex XIII (4)	The statement referred to in the introductory part of Section 1 shall be kept for a period of at least 10 years after the device has been placed on the market. In the case of implantable devices, the period shall be at least 15 years. Section 8 of Annex IX shall apply.	To be done	Compliant if the documentation is planned to be stored for at least 10 years.
Annex XIII (5)	The manufacturer shall review and document experience gained in the post-production phase, including from PMCF as referred to in Part B of Annex XIV, and implement appropriate means to apply any necessary corrective action, In that context, it shall report in accordance with Article 87(1) to the competent authorities any serious incidents or field safety corrective actions or both as soon as it learns of them.	To be done	Have a post-market surveillance (PMS) process and documents for all manufactured custom-made devices and patient solutions. Using the supplied process will make this requirment compliant.