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MDR – Compliance Checklist

Distributor

MDR Article	MDR Requirement	Compliance Status	Comment
Article 14 (1)	When making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable.	To be done	Compliant if all requirements of article 14 are fulfilled.
Article 14 (2)	Before making a device available on the market, distributors shall verify that all of the following requirements are met: (a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up; (b) the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(11); (c) for imported devices, the importer has complied with the requirements set out in Article 13(3); (d) that, where applicable, a UDI has been assigned by the manufacturer.	To be done	Compliant if either the factors are checked directly or a contract with the manufacturer of bought devices exists that outlines the competences of each side.
Article 14 (2)	In order to meet the requirements referred to in points (a), (b) and (d) of the first subparagraph the distributor may apply a sampling method that is representative of the devices supplied by that distributor.	To be done	If devices are checked, the use of a known and scientific sampling method to be compliant is allowed.
Article 14 (2)	Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not make the device available on the market until it has been brought into conformity, and shall inform the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. Where the distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which it is established.	To be done	If you are aware that you are not allowed to sell unchecked devices this is compliant.
Article 14 (3)	Distributors shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.	To be done	Compliant if either the factors are checked directly or a contract with the manufacturer of bought devices exists that outlines the competences of each side.
Article 14 (4)	Distributors that consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, the manufacturer's authorised representative and the importer. Distributors shall co-operate with the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer, and with competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken. Where the distributor considers or has reason to believe that the device presents a serious risk, it shall also immediately inform the competent authorities of the Member States in which it made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.	To be done	Be able to get in contact with manufacturers about complaints and non-conformities. If the used vigilance process is used, this shall be covered.
Article 14 (5)	Distributors that have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. They shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative and the importer informed of such monitoring and provide them with any information upon their request.	To be done	Be able to get in contact with manufacturers about complaints and non-conformities. If the used vigilance process is used, this shall be covered.
Article 14 (6)	Distributors shall, upon request by a competent authority, provide it with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a device.	To be done	You need to work on request with your competent authority and provide necessary documents. This is assumed to be generally compliant and is not different from the current situation under the MDD.
Article 14 (6)	Distributors shall be considered to have fulfilled the obligation referred to in the first subparagraph when the manufacturer or, where applicable, the authorised representative for the device in question provides the required information. Distributors shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. Distributors, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, grant access to the device.	To be done	You need to work on request with your competent authority and provide necessary documents. This is assumed to be generally compliant and is not different from the current situation under the MDD.