

Home Care Service Providers' Obligations under the Medical Devices Regulation

Introduction

The Medical Device Regulation (MDR) becomes applicable as of the 26th of May 2021.

The objective of this Technical Bulletin is to give guidance on the interpretation of this regulation for Home Care Service Providers (HSP) and to provide recommendations on how to implement the requirements of this regulation.

Scope

The MDR introduces the concept of 'Economic Operators'. Based on this concept, the HSP is falling under the category of distributor, although under some circumstances described in the table below, the HSP can also be manufacturer and/or importer.

The relevant articles for distributors' activities are covered in chapter II of the MDR describing obligations of 'Economic Operators'.

The individual situation of the HSP can vary depending on the activities performed by the HSP. If also a role of manufacturer or importer applies, this is outside the scope of this Technical Bulletin, and the relevant sections of the MDR for manufacturer and/or importer should be complied with.

This Technical Bulletin looks at the MDR current revision and does not cover national regulations that may apply.

Table reading guidance

Column 'Art', 'Par' and 'Title' refers to the original articles in the MDR.

The full text of the article is shown as well in the table.

'Keyword' helps the reader to navigate through the table by indicating the main subject of the article.

In the final column, EIGA HSP's interpretation and/or recommendation is given. It reflects the current status of understanding and can be subject to changes.

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Art	Par	Title	Keyword	Full text	EIGA interpretation and/or recommendation
2	-	Definitions	Manufacturer	(30) 'manufacturer' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;	EIGA members are manufacturers of Medical Devices. The definition of 'manufacturer' does not apply to most of the EIGA Homecare Service Providers.
2	-	Definitions	Distributor	(34) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;	EIGA Homecare Service Providers are considered to be 'distributors'.
2	-	Definitions	User	(37) 'user' means any healthcare professional or lay person who uses a device;	The patient is primarily considered to be the 'user' of medical devices provided by the HSP. EIGA HSP may be considered to be 'users' under certain conditions. For example: when operating polysomnography devices for sleep analysis.
14	2	General obligations of distributor	Device Compliance	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. 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.	These requirements shall be reflected in the Standard Operating procedures of the HSP. The complete check (see Annex 1) shall be performed when the medical device is added to the product portfolio. When devices are purchased, they shall be checked on a risk based statistical sampling basis to verify the checks written

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				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.	under art. 14 a, c and d. The materiovigilance procedures shall comply to the requirements of the MDR.
14	3	General obligations of distributor	Storage and transport conditions	Distributors shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.	The HSP shall follow the storage or transport condition written in the instructions for use. Please be aware that the storage or transport conditions between (gas)packages and medical devices differ from each other (for example temperature and humidity).
14	4	General obligations of distributor	Non-conformities and serious risk; Implementation of corrective actions	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.	The materiovigilance procedures shall comply to the requirements of the MDR. Nonconformity and recall procedures shall be in place. The communication pathways should be explicitly mentioned in the procedures.
14	5		Inform of complaints and	Distributors that have received complaints or reports from healthcare professionals, patients or users about	The distribution aspects of MDR shall be covered by the Quality

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			suspected incidents; Register of complaints, non-conforming devices	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.	Management System of the HSP.
14	6		Cooperation with competent authorities	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.	Be aware that as a HSP you are responsible to verify conformity of devices that are put to the market. This should be adequately covered in the QMS. To ensure this conformity, see also point 14.2.
16	1.c		Unpacking	A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if it does any of the following: (c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected. 2. For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements: changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the device in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the packaging that is necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.	The HSP does not assume the role of manufacturer in case that, in order to provide the individual patient, he carries out the unpacking of a device received in multipacks if the single unit within the multipack is individually packed, labelled and traceable.
22	1		Systems or procedure packs	1. Natural or legal persons shall draw up a statement if they combine devices bearing a CE marking with the following other devices or products, in a manner that is compatible with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order	If the HSP offers and supplies only products in accordance with the intended uses envisaged by the respective manufacturers,

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