TECHNICAL BULLETIN

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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

				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

			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,

				to place them on the market as a system or procedure pack: (a) other devices bearing the CE marking;	and according to the prescription/request; If In the delivery documentation and in its own traceability systems, the HSP identifies the devices individually on the basis of the traceability information provided by the individual manufacturers and - at the patient's home- Then the HSP operates the commissioning without modifying the prescribed application, thus he is NOT placing on the market a system or procedure pack.
25	-	Identification within the supply chain	Traceability	1. Distributors and importers shall co-operate with manufacturers or authorised representatives to achieve an appropriate level of traceability of devices. 2. Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 10(8): (a) any economic operator to whom they have directly supplied a device; (b) any economic operator who has directly supplied them with a device; (c) any health institution or healthcare professional to which they have directly supplied a device.	Interpretation of the period meant by point 2 is 10 years or the expected lifetime of a device. It is a recommendation to use the UDI for traceability purposes, but not an obligation. Only for Class III products (and/or implantable devices) the traceability use of the UDI is obligatory. According to Annex 6.4.7. for Home Care purposes, the traceability records shall also be

					in human readable format.
30	2	Electronic system for registration of economic operators	Distributor registration	1. The Commission, after consulting the MDCG, shall set up and manage an electronic system to create the single registration number referred to in Article 31(2) and to collate and process information that is necessary and proportionate to identify the manufacturer and, where applicable, the authorised representative and the importer. The details regarding the information to be provided to that electronic system by the economic operators are laid down in Section 1 of Part A of Annex VI. 2. Member States may maintain or introduce national provisions on registration of distributors of devices which have been made available on their territory. 3. Within two weeks of placing a device, other than a custom-made device, on the market, importers shall verify that the manufacturer or authorised representative has provided to the electronic system the information referred to in paragraph 1. Where applicable, importers shall inform the relevant authorised representative or manufacturer if the information referred to in paragraph 1 is not included or is incorrect. Importers shall add their details to the relevant entry/entries.	EIGA members have to be aware that when they are importers, they need to comply with this section of the MDR. Even if not required by MDR, national legislation can require registration of the distributors.
27	8	Unique Device Identification system	Storage of UDI data	8. Economic operators shall store and keep, preferably by electronic means, the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to: — class III implantable devices; — the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 11.	Covered in the comments on article 25.
95	3	Procedure for dealing with devices presenting an unacceptable risk to health and safety	Application of corrective actions	1. Where, having performed an evaluation pursuant to Article 94, the competent authorities find that the device presents an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall without delay require the manufacturer of the devices concerned, its authorised representative and all other relevant economic operators to take all appropriate and duly justified corrective action to bring the device into compliance with the requirements of this Regulation relating to the risk presented by the device and, in a manner that is proportionate to the nature of the risk, to restrict the making available of the	

				device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it, within a reasonable period that is clearly defined and communicated to the relevant economic operator. 2. The competent authorities shall, without delay, notify the Commission, the other Member States and, where a certificate has been issued in accordance with Article 56 for the device concerned, the notified body that issued that certificate, of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 100. 3. The economic operators as referred to in paragraph 1 shall, without delay, ensure that all appropriate corrective action is taken throughout the Union in respect of all the devices concerned that they have made available on the market. 4. Where the economic operator as referred to in paragraph 1 does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate measures to prohibit or restrict the making available of the device on their national market, to withdraw the device from that market or to recall it. The competent authorities shall notify the Commission, the other Member States and the notified body referred to in paragraph 2 of this Article, without delay, of those measures, by means of the electronic system referred to in Article 100. 5. The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification and tracing of the non-compliant device, the origin of the device, the nature of and the reasons for the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. 6. Member States other than the Member State initiating the procedure shall, without delay, inform the Commission and the other Member States, by means of the electronic system referred to in Article 100, of any additional relevant	The role of the HSP is to use its traceability information to perform the required corrective actions as described in the QMS.

				information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned. In the event of disagreement with the notified national measure, they shall, without delay, inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 100. 7. Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of any measures taken by a Member State, those measures shall be deemed to be justified. In that case, all Member States shall ensure that corresponding appropriate restrictive or prohibitive measures, including withdrawing, recalling or limiting the availability of the device on their national market, are taken without delay in respect of the device concerned.	
16				Article 16 Cases in which obligations of manufacturers apply to importers, distributors or other persons 1. A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if it does any of the following: (a) makes available on the market a device under its name, registered trade name or registered trade mark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation; (b) changes the intended purpose of a device already placed on the market or put into service; (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. The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in point (30) of Article 2, assembles or adapts for an individual patient a device already on the market without changing its intended purpose. 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	If the HSP does not want to be considered as manufacturer when co-branding or co-labelling, it is necessary that the label of the original remains clearly visible, and the co-branding or co-labelling is covered by a contract between the manufacturer and the HSP As long as repackaged goods maintain the original manufacturers label and traceability information, it is

				with the applicable requirements: (a) provision, including translation, of the information supplied by the manufacturer, in accordance with Section 23 of Annex I, relating to a device already placed on the market and of further information which is necessary in order to market the device in the relevant Member State; (b) 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. 3. A distributor or importer that carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate on the device or, where that is impracticable, on its packaging or in a document accompanying the device, the activity carried out together with its name, registered trade name or registered trade mark, registered place of business and the address at which it can be contacted, so that its location can be established. Distributors and importers shall ensure that they have in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by a means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. The quality management system shall cover, inter alia, procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it into conformity with this Regulation. 4. At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities mentioned in points (a) and (b) of paragraph 2 shall inform the manufacturer and the competent authority of the Member State in which they plan to make the device available of the intention to make the relabelled or	considered unnecessary to perform the obligations under 3 and 4. If however, through repackaging, the original label and traceability information of the original manufacturer is compromised, it is obliged to follow points 3 and 4 of this article. As for translations of instructions for use, any translations of instructions for use should be performed under a certified QMS and notified to the original manufacturer and the competent authority, as per points 3 and 4. The recommendation is to have the manufacturer do the translation.

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				repackaged device available and, upon request, shall provide the manufacturer and the competent authority with a sample or mock-up of the relabelled or repackaged device, including any translated label and instructions for use. Within the same period of 28 days, the distributor or importer shall submit to the competent authority a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system of the distributer or importer complies with the requirements laid down in paragraph 3.	
22				Article 22 Systems and 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 to place them on the market as a system or procedure pack: (a) other devices bearing the CE marking; (b) in vitro diagnostic medical devices bearing the CE marking in conformity with Regulation (EU) 2017/746; (c) other products which are in conformity with legislation that applies to those products only where they are used within a medical procedure or their presence in the system or procedure pack is otherwise justified. 2. In the statement made pursuant to paragraph 1, the natural or legal person concerned shall declare that: (a)they verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and have carried out their activities in accordance with those instructions; (b) they packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together; (c) the activity of combining devices and, if applicable, other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation. 3. Any natural or legal person who sterilises systems or procedure packs referred to in paragraph 1 for the purpose of placing them on the market shall,	When putting together procedure or therapy packs consisting of all CE marked components, a declaration according to point 1 has to be made and labelling according to § 5 needs to be done. When putting together procedure or therapy packs with one or more non-CE marked component(s), the distributor takes on the manufacturers responsibility. It is considered as not subject to this article when the HSP provides individual CE marked components to the patient.

				at their choice, apply one of the procedures set out in Annex IX or the procedure set out in Part A of Annex XI. The application of those procedures and the involvement of the notified body shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile packaging is opened or damaged. The natural or legal person shall draw up a statement declaring that sterilisation has been carried out in accordance with the manufacturer's instructions. 4. Where the system or procedure pack incorporates devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose, or where the sterilisation has not been carried out in accordance with the manufacturer's instructions, the system or procedure pack shall be treated as a device in its own right and shall be subject to the relevant conformity assessment procedure pursuant to Article 52. The natural or legal person shall assume the obligations incumbent on manufacturers. 5. The systems or procedure packs referred to in paragraph 1 of this Article shall not themselves bear an additional CE marking but they shall bear the name, registered trade name or registered trade mark of the person referred to in paragraphs 1 and 3 of this Article as well as the address at which that person can be contacted, so that the person's location can be established. Systems or procedure packs shall be accompanied by the information referred to in Section 23 of Annex I. The statement referred to in paragraph 2 of this Article shall be kept at the disposal of the competent authorities, after the system or procedure pack has been put together, for the period that is applicable under Article 10(8) to the devices that have been combined. Where those periods differ, the longest period shall apply.	If the items are individually mentioned on the delivery note, it is considered as not being subjected to this article. If however the different items are mentioned under one item on the delivery note, it is considered to be subject to the obligations from this article. Also when using a Medical Device outside its intended scope of use, the responsibility as manufacturer applies. .

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