Newsletter 2019/06

Importer and Distributor under MDR

The roles and responsibilities of importers and distributors will significantly change and increase with the MDR. Traceability is one keyword of the MDR. All economic operators (manufacturers, authorized representatives, importers and distributors) shall cooperate to enable traceability of medical devices. To realize this, obligations for importers (Article 13) and distributors (Article 14) were included in the new regulation. Please find enclosed the corresponding articles as excerpts of the MDR.

Importer

In the MDR the importer is defined as any natural or legal person established within the European Union that places a device from a third country on the Union market. In this function importers have the responsibility to ensure that only MDR-conform devices are placed on the market.
Thus, before placing on the market the importer shall verify for each device in each shipment that the following applies:

- Device is CE marked.
- EU declaration of conformity has been drawn up.
- The manufacturer is identified.
- An authorized representative has been designated by the manufacturer.
- MDR-conform label and instruction for use.
- Indication of the importer (with name and address) given on the device or on its packaging or in a document accompanying the device.
  (Pay special attention in case you have several importers for a single product. In that case, each importer shall be indicated accordingly on products which they import.)
- UDI has been assigned by the manufacturer, where applicable.

Further obligations of the importer are:

- In case the importer considers a device as non-conform to MDR, the device shall not be placed on the market.
- Manufacturer and the authorized representative shall be informed about non-conformities by the importer.
- In the event of serious risk or falsified device the competent authorities have to be informed by the importer.
- EUDAMED registration of the importer (Article 31).
- Verification of the device registration in EUDAMED by the importer (Article 29).
- Control of storage or transport conditions so that they are in compliance with manufacturer's requirements when the device is under the importer's responsibility.
- Keep a register of complaints.
- Cooperate with the manufacturer, authorized representative, distributors and competent authorities.
- Inform manufacturer and its authorized representative about complaints.
- Keep a copy of the EU declaration of conformity and relevant certificates, if applicable.

Distributor

The definition of the distributor is 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. The obligations for distributors are less stringent than for importers but still challenging.

Using representative sampling the distributors shall ensure that the distributed devices are fulfilling the following requirements:

- Device is CE marked.
- EU declaration of conformity has been drawn up.
- MDR-conform label and instruction for use (written in an official language as determined by the Member State in which the device is made available).
- UDI has been assigned by the manufacturer, where applicable.
- Indication of the importer, where applicable.

Further obligations of the distributor are:

- Control storage and transport conditions to comply with the manufacturer's recommendations.
- In case the distributor considers a device as non-conform to MDR, the device shall not make available on the market.
- Manufacturer, the authorized representative, and importer shall be informed about non-conformities.
- In the event of serious risk or falsified device the competent authorities have to be informed.
- Keep a register of complaints.
- Cooperate with the economic operators as well as the competent authorities.

Conclusion

Manufacturers shall make sure that their importers and distributors will work in compliance with the new Medical Device Regulation MDR. It might be advisable to draw up specific agreements which define the respective obligations and the cooperation between the manufacturer and its economic operators.

For more detailed information, please do not hesitate to contact us:

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Excerpt of

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Article 13

General obligations of importers

1. Importers shall place on the Union market only devices that are in conformity with this Regulation.

2. In order to place a device on the market, importers shall verify that:

   a. the device has been CE marked and that the EU declaration of conformity of the device has been drawn up;

   b. a manufacturer is identified and that an authorised representative in accordance with Article 11 has been designated by the manufacturer;

   c. the device is labelled in accordance with this Regulation and accompanied by the required instructions for use;

   d. where applicable, a UDI has been assigned by the manufacturer in accordance with Article 27.
   Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not place the device on the market until it has been brought into conformity and shall inform the manufacturer and the manufacturer's authorised representative. Where the importer 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 the importer is established.

3. Importers shall indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.

4. Importers shall verify that the device is registered in the electronic system in accordance with Article 29. Importers shall add their details to the registration in accordance with Article 31.

5. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I and shall comply with the conditions set by the manufacturer, where available.

6. Importers shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and provide the

manufacturer, authorised representative and distributors with any information requested by them, in order to allow them to investigate complaints.

7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and its authorised representative. Importers shall co-operate with the manufacturer, the manufacturer's authorised representative and the competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or recall it is taken. Where the device presents a serious risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 56 for the device in question, giving details, in particular, of the non-compliance and of any corrective action taken.

8. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and its authorised representative.

9. Importers shall, for the period referred to in Article 10(8), keep a copy of the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56.

10. Importers shall cooperate with competent authorities, at the latters' request, on any action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market. Importers, upon request by a competent authority of the Member State in which the importer has its registered place of business, shall provide samples of the device free of charge or, where that is impracticable, grant access to the device.

Article 14

General obligations of distributors

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.

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.

3. 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.

4. 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.

5. Distributors shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.

6. 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.

   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.

7. 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.

   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.