

## 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

在欧盟新法规MDR中进口商和经销商的角色相比旧法规有很大变化，其责任也明显增加。可追溯性是MDR的一个关键词。所有经营主体（制造商，授权代表，进口商和经销商）应合作以实现医疗器械的可追溯性。为了实现这一点，新法规中规定了进口商（[第13条](#)）和经销商（[第14条](#)）的职责义务。我们亦在本文后面附上相应的MDR摘录。

### 进口商

在MDR中，进口商定义为任何在欧盟境内的自然人或法人，其把来自第三国的器械投放到欧盟市场上。进口商有责任确保仅将符合MDR的器械投放市场。

因此，进口商在投放市场之前，应对每批货物中的每种器械进行以下验证：

- 器械带有CE标记。
- 签署了欧盟符合性声明。
- 有明确制造商信息。
- 制造商已指定了授权代表。
- 标签和使用说明符合MDR的要求。
- 在器械或器械包装或随器械附加的文件中写明了进口商信息（包括名称和地址）。

（请特别注意，如果一个产品有多个进口商，则须在产品上相应地注明每个进口商。）

- 如果适用，制造商已经分配了UDI。

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:

进口商的其他义务是:

- 如果进口商认为某器械不符合MDR，则不得投放市场。
- 进口商应将该器械的不合格情况告知制造商和授权代表。
- 如果存在严重风险或器械伪造，进口商必须通知主管当局。
- 在EUDAMED数据库完成进口商注册（MDR第31条）。
- 在EUDAMED中核实器械产品注册（MDR第29条）。
- 控制存储或运输条件，使其符合制造商的要求。
- 保留投诉记录。
- 与制造商，授权代表，经销商和主管部门合作。
- 将投诉告知制造商及其授权代表。
- 保留欧盟符合性声明和相关证书的副本（如果适用）。

## 经销商

经销商的定义是供应链中除制造商或进口商外，将产品投放市场直到产品被投入使用的任何自然人或法人。经销商的职责义务不如进口商严格，但仍具有挑战性。经销商应进行有代表性的采样来确保其经销的器械满足以下要求:

- 器械带有CE标记。
- 签署了欧盟符合性声明。
- 标签和使用说明符合MDR的要求（以器

- 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 be made 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.

械销售目的国当地的官方语言编写)。  
-如果适用, 制造商已经分配了UDI。  
-标明了进口商信息(如适用)。

经销商的其他职责是:

- 控制储存和运输条件以符合制造商的建议。
- 如果经销商认为某器械不符合MDR, 则不得投放市场。
- 应将该器械的不合格情况告知制造商, 授权代表和进口商。
- 如果存在严重风险或器械伪造, 必须通知主管当局。
- 保留投诉记录。
- 与各经营主体以及主管部门合作

## 结论

制造商应确保其进口商和经销商将符合新医疗器械法规 MDR。建议制定具体协议以确定定义制造商与各个经营主体之间的合作, 以及各自的职责。

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

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**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 latter's 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.