MD REGULATORY DIGEST

FOCUS ON

NEW ECONOMIC OPERATORS

The definitions of **importer**, **distributor** and **authorised representative** have been introduced in the MDR. This implies that the **obligations and responsibilities** of these economic operators have been explicitly defined.
Definitions are given in Art. 2, and their obligations are stated in Art. 11 for the authorised representative, Art. 13 for the importer and Art. 14 for the distributor.

AUTHORISED REPRESENTATIVE

The MDR clearly states that **any manufacturer that is not established in an EU Member state** shall designate a **sole authorised representative** in order to place its device on the European market. The mandate shall be accepted in writing by the authorised representative and shall be effective **at least for all devices of the same generic device group**.
The authorised representative act on the manufacturer's behalf in relation to specified tasks with regard to its obligations under the MDR.
In case of change of authorised representative, Art. 12 shall be applied.

IMPORTER & DISTRIBUTOR

The first receiver of a device on the EU market is the importer. The following ones are distributors.
Contrary to the authorised representative, one type of device can have several importers.
The most important idea is that **each importer and distributor is responsible** for the devices they place on the European market. Namely,

- Economic operators shall **verify that it meets MDR requirements** before making a device available on the market. Where an importer or a distributor **considers that a device is not in conformity** with the requirements, it shall not make the device available on the market until it has been brought into conformity.
- It shall not make a device available on the market neither if it is not CE marked, if no UDI has been assigned, or **any other situation of non-conformity**.
- Of course, any economic operator shall **cooperate with competent authorities** upon request.

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