General obligations of importers
Art. 13

Guiding you through the MDR, one article at a time.

Importing medical devices is not as simple as importing other goods into the EU. Importers have special obligations and need to comply with the regulations.
In this fast fact, we help you understand the general obligations of importers.

If you need help or guidance in importing your products, contact us!

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.

For more information, please review:

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General obligations of importers

2. (continued) 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.

For more information, please review:

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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.

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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.

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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.

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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.

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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.

For more information, please review:

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Takeaway

Article 13 clearly sets out the general obligations of importers to **place a product on the market** within the EU:

- If an importer believes that a product does **not comply** with these requirements, he must **avoid** placing it on the market at all costs.
- The importer's contact details are **visibly** marked on the product or packaging, or on accompanying documents.
- In the event of a serious risk posed by the product or a counterfeit, the competent authority shall be informed **immediately.**

For more information, please review:

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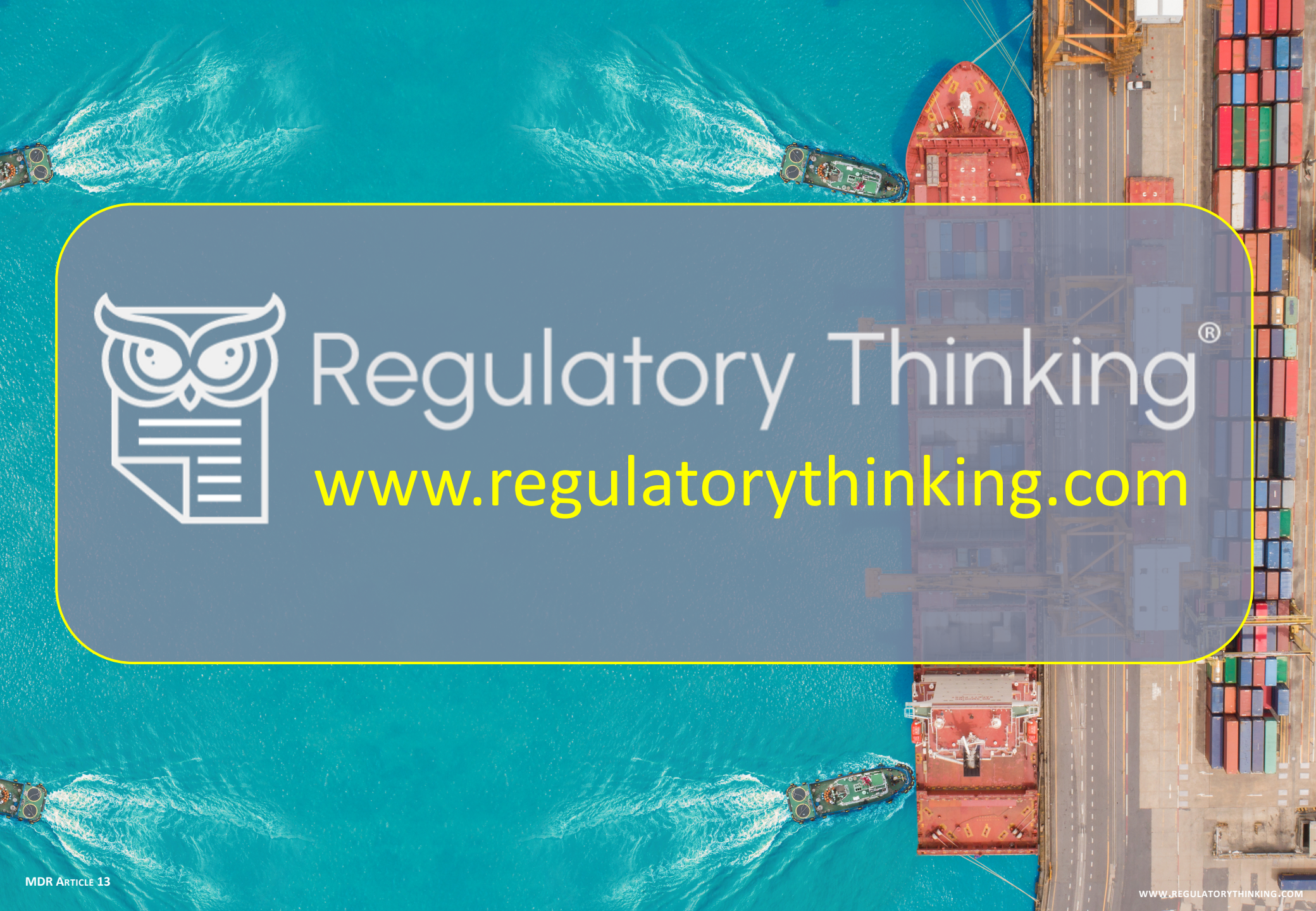
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