Regulatory Thinking®

Implant card and information to be supplied to the patient with an implanted device

Art. 18

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

For most implantable devices, the manufacturer is required to provide certain information directly with the product.
In this fast fact, we will help you understand the information to be supplied to the patient with an implanted device.

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

Implant card and information to be supplied to the patient with an implanted device

1. The manufacturer of an implantable device shall provide together with the device the following:
(a) information allowing **the identification of the device**, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer;
(b) any **warnings, precautions or measures** to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;
(c) any **information about the expected lifetime** of the device and any necessary follow-up;
(d) any **other information to ensure safe use** of the device by the patient, including the information in point (u) of Section 23.4 of Annex I.

For more information, please review:

Article 18 MDR

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1. (continued) The information referred to in the first subparagraph shall be provided, for the purpose of making it available to the particular patient who has been implanted with the device, by any means that allow **rapid access to that information** and shall be stated in the language(s) determined by the concerned Member State. The information shall be written in a way that is readily understood by a lay person and shall be updated where appropriate. Updates of the information shall be made available to the patient via the website mentioned in point (a) of the first subparagraph.

In addition, the manufacturer shall provide the information referred to in point (a) of the first subparagraph on an **implant card delivered with the device**.

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2. Member States shall require health institutions to make the information referred to in paragraph 1 available, by any means that allow rapid access to that information, to any patients who have been implanted with the device, together with the implant card, which shall bear their identity.

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3. The following implants shall be exempted from the obligations laid down in this Article: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this list by adding other types of implants to it or by removing implants therefrom.

For more information, please review:

Article 18 MDR

Takeaway

Art. 18 specifies exactly what information a manufacturer must provide about an implantable device, which includes:

- *all information for the identification of the device*
- *all warnings and precautions or precautionary measures with regard to interactions*
- *expected lifetime of the product*
- *other information on safe use*

This information must be summarized in an implantation certificate. Furthermore, Art. 18 (3) exempts a few implants from this article.

For more information, please review:

Article 18 MDR


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