European Commission

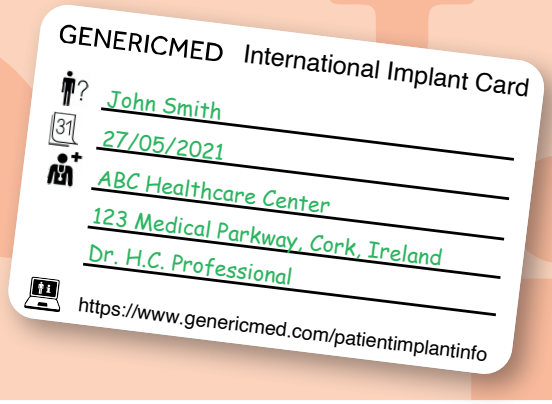
Factsheet for Manufacturers of Implantable Medical Devices

This factsheet is aimed at manufacturers of implantable medical devices and relates to the application of Article 18 of Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices. For further information and specific examples of implant card designs, consult the guidance document ***MDCG 2019 8 V2.***

Background:

The new Regulation (EU) 2017/745 on medical devices (MDR) puts in place a reinforced legal system for medical devices that prioritises transparency and patient access to information. With these goals in mind, the Regulation introduces a new requirement for implantable medical device manufacturers to provide an **'implant card' (IC)**, offering patients easy access to all relevant information concerning the device with which they have been implanted.

What You Need to Know About Implant Cards



Purpose of an Implant Card

Implant cards serve various purposes. They:

Enable the patient to identify the implanted device and to get access to safety-related information (e.g. via the EUDAMED database website).

Enable patients to identify themselves as persons requiring special care in certain situations, such as during security checks, and inform emergency clinical staff or first responders about the special care/needs of specific patients.

Medical Devices Requiring an Implant Card

Manufacturers of **implantable medical devices** certified according to the MDR should provide the required information on an implant card to be delivered with the device, **unless the device is exempt by virtue of MDR Article 18 paragraph 3**.

The following implants **are exempt** from the implant card obligations: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.

Requirements for Manufacturers:

Under Article 18 paragraph 1, point (a), of the MDR, manufacturers should provide the following necessary information on the IC (preferably on the card itself or, alternatively, as stickers to be placed by the clinician).

1. **Device name;**
2. **Device type;**
3. **Unique device identification (UDI) – the UDI should be in automatic identification and data capture (AIDC) format, e.g. linear or 2D-barcodes, and the UDI device identifier (UDI-DI) should be in human-readable format;**
4. **Serial number or, where applicable, lot or batch number;**
5. **Name and address of the manufacturer of the medical device;**
6. **Website of the manufacturer of the medical device.**

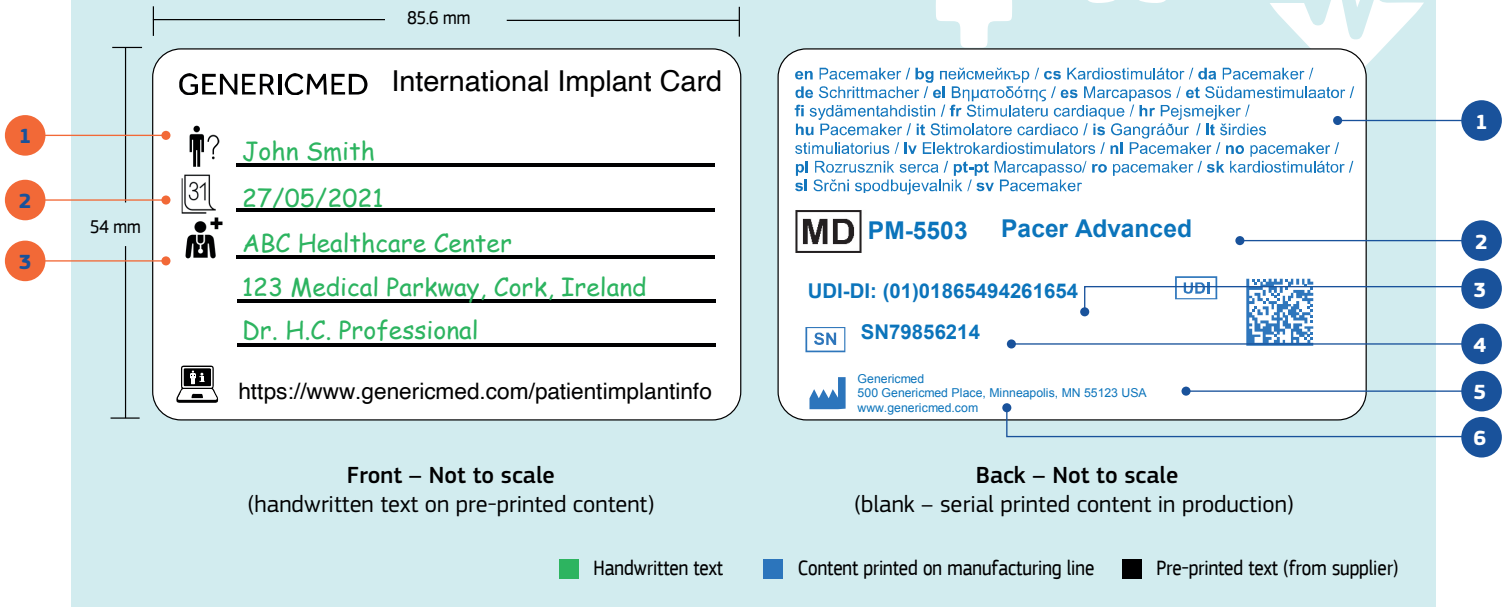
In addition, the manufacturer should design the IC in such a way that it includes the following blank fields to be filled out by the implanting healthcare institution or healthcare provider:

1. **Name of the patient or patient ID;**
2. **Date of implantation.**
3. **Name and address of the healthcare institution that performed the implantation;**

Size Requirements:

The outer dimensions of the IC should be the same as those of a credit card, ATM card or ID card (85.6 mm × 53.98 mm) with a radius of 2.88–3.48 mm.

Fig 1: Sample Implant Card



Front – Not to scale
(handwritten text on pre-printed content)

Back – Not to scale
(blank – serial printed content in production)

Handwritten text | Content printed on manufacturing line | Pre-printed text (from supplier)

See *MDCG 2019-8 V2*, Annex 1 for additional IC examples and information.

Ease of Reading Requirements:

The text provided on the IC, and on the instructions for completing the IC by the healthcare institution or healthcare provider, must be legible and at least 2 millimetres high. 'Text' includes any number, letter or symbol, including letters and numbers in a symbol.

The information shall be written in such a way that it can be readily understood by a layperson, and provided by any means that allow rapid access to the information, in the language(s) determined by the relevant Member State.

Use of Symbols

To avoid national versions of the IC, the use of symbols is advisable.

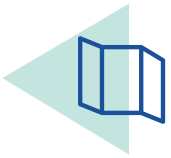
An explanation of the symbols on the IC should be provided in the instructions to **the healthcare provider on how to complete the IC**, or on the back of the IC, if space allows. For a list of symbols recommended for use on the IC, consult ***MDCG 2019-8 V2***.

Use of Language in a Member State

The information provided on the IC should be written in the language(s) required by the relevant Member State.

Despite the nearly complete list of symbols for fields on the IC, there is currently no symbol available for the required field "Device Type". The lack of a symbol and the purpose of this field make it necessary to provide the information on the device type in the language accepted/required by the relevant Member State.

There are several possibilities available to provide this information in the necessary languages, e.g., the information is already printed on the IC in the different languages, or stickers are provided with the IC and the healthcare professional selects the correct one, for example.



Use of an Implant Card Leaflet for Healthcare Professionals

Device manufacturers should provide, **together with the IC**, instructions for the healthcare professional on how to complete the IC and to explain the symbols used. This information should be provided in the language(s) required by the relevant Member State. For this reason, a leaflet containing the relevant information, to be provided together with the IC and the implantable device, is the **recommended solution**.

Updates to the IC Information:

IC information should be updated where and when appropriate. Updates of the information should be made available to the patient via a website, which should be indicated on the IC.

Implantable Systems

If an implantable device contains implantable components that might be replaced by other (or the same) components, for example in case of a later revision, the manufacturers should consider the use of a System IC. Consult ***MDCG 2019-8 V2,*** Annex I for an example.

Frequently Asked Questions

1. *Do ICs need to be provided retrospectively for devices already placed on the market under Directive 90/385/EEC or Directive 93/42/EC ?*

No. Article 18 requirements apply only to devices placed on the market under Regulation (EU) 2017/745.

2. *Which patient information are manufacturers of implantable devices required to supply with the device?*

In addition to the information on the IC itself (Article 18 paragraph 1, point (a)), the manufacturer must provide the following information (Article 18 paragraph 1, points (b)-(d)) together with the device. The manufacturer may do this by any means that allow rapid access to such information in a language(s) determined by the concerned Member State.

- 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;
- Any information about the expected lifetime of the device and any necessary follow-up;
- Any other information to ensure safe use of the device by the patient, including qualitative and quantitative information on the materials and substances to which patients can be exposed.

3. *Are manufacturers of implantable medical devices required to have a website through which they can provide required device information for patients receiving an implant?*

Yes. The manufacturer's website is to be included on the IC, in accordance with Article 18 paragraph 1, point (a).

4. *Are there any GDPR privacy concerns regarding the identity of the patient?*

According to Article 18 paragraph 2, only the physical implant card provided to the patient by the healthcare institution/provider should bear the identity of the patient. The patient's name will be completed at the point of care and the implant card is then given to the patient.

5. *Can the UDI Carrier on the IC be machine readable?*

The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific device on the market. The UDI is comprised of the device identifier (UDI-DI) and the production identifier (UDI-PI). The UDI Carrier (the representation of the UDI) is to be included on the IC in automatic identification and data capture (AIDC) format, e.g. linear or 2D-Barcodes, and the IC **must** include the UDI-DI in human-readable format.

6. *Does the IC need to include both UDI-DI and UDI-PI?*

Yes. Both the UDI-DI and UDI-PI must be on the implant card.

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https://ec.europa.eu/health/md_newregulations/overview_en

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