Instructions for completing the implant card

Based on the regulation (EU) 2017/745 (MDR), manufacturers of human implantology products are required to provide an implant card (Implant Card, IC) for implants class III and IIb not exempted by the Regulation.

The implant card is a standard sized card with standardized data content, which the manufacturer is obliged to provide for the specific products and which is handed over to the patient by the healthcare institution in order to enable the identification of the implanted device for the patient and, later, for the additional professional staff who care for the patient and also provide access to safety-related information for the additional specialist staff caring for the patient.

With the exception of the product groups defined by Regulation (EU) 2017/745, the data of the plastic card that is part of the packaging of implants class IIb and III contains the data of the implant used for the patient's treatment, which is the basic condition for follow-up, as well as the most important data of the specialist institution performing the surgery and the circumstances of the implantation. The manufacturer records the product-specific data in pre-printed form on the plastic card. However, it is the user's (health care provider institution's) responsibility to fill in the blank fields on the back of the card with the relevant data. The institution must hand over the card containing handwritten filled-in data to the patient and inform the patient about the function of the card.

Front page of a sample implant card (*Figure 1*), on which the manufacturer prints the product-specific data on the card:

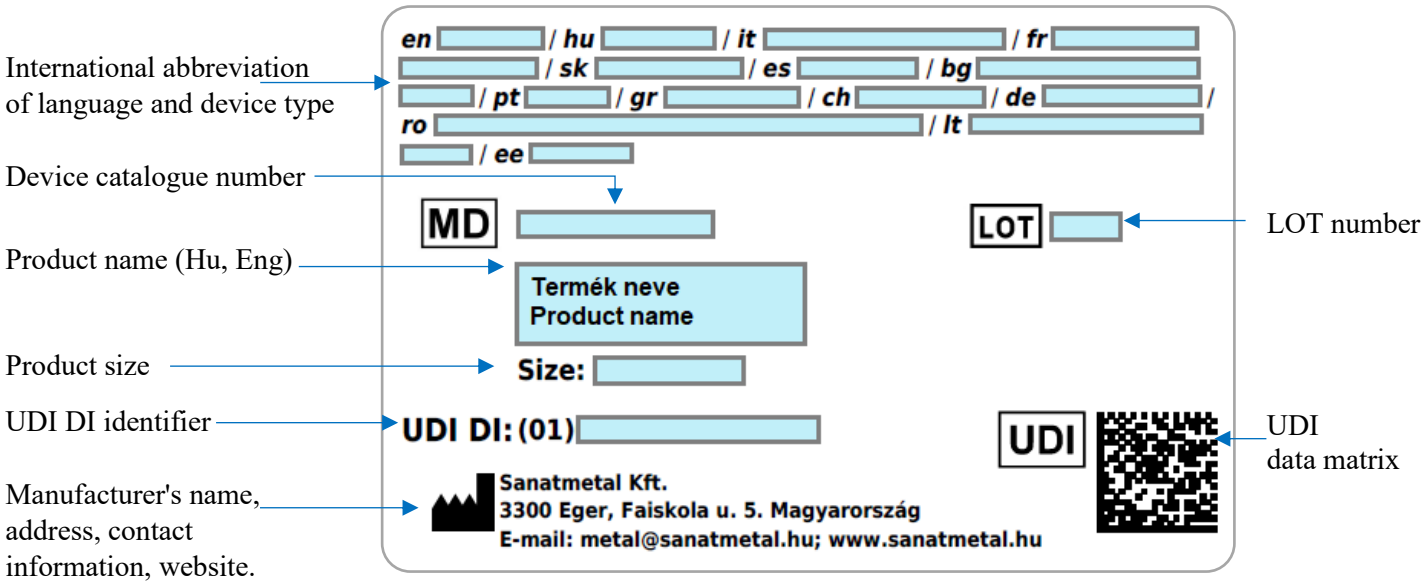


Figure 1

The lines marked with a * on the standard back of the implant card (*Figure 2*) must be filled in by the health care provider institution with the specific data of the operation. According to this, the name or ID of the patient, the date (day) of the operation: in year-month-day format, as well as the name and address of the medical institution/provider carrying out the implantation, and the name of the doctor providing care must be entered on the card.

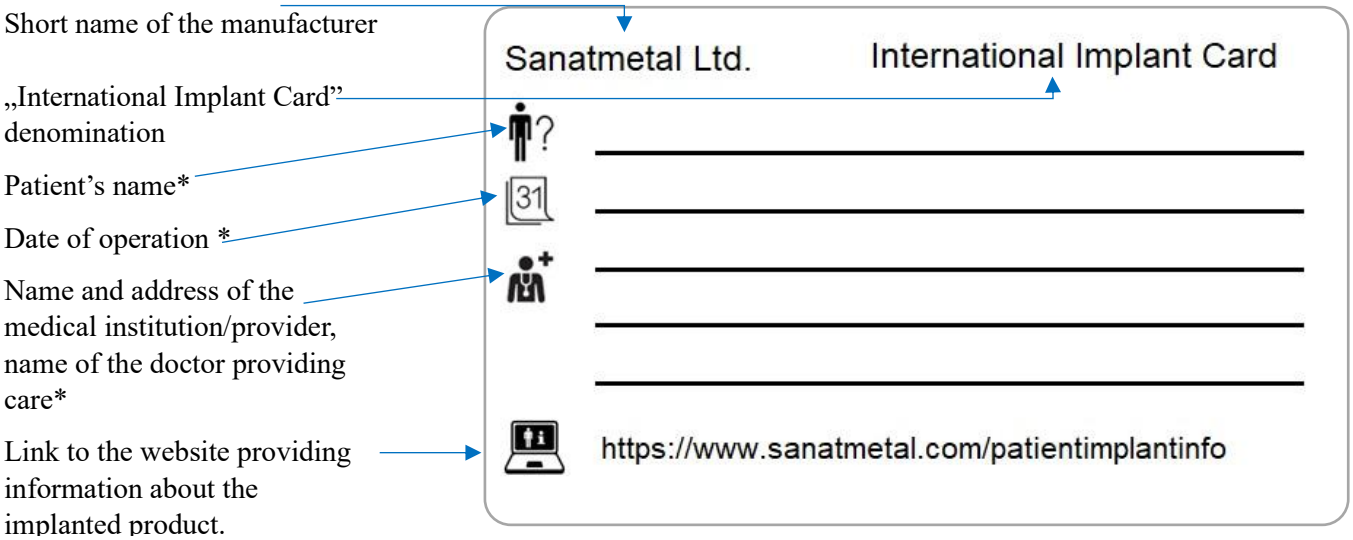


Figure 2

Explanation of the international pictograms used on the card accompanying the implant:

Pictogram	Source	Meaning	Explanation
MD	ISO 15223-1, 5.7.7	**M**edical **D**evice	It means any instrument, tool, device that is used to cure sick or injured people, so it has a medical purpose.
LOT	ISO 15223-1, 5.1.5 ISO 7000-2492	LOT number	Production batch number, it indicates the medical devices that were manufactured at the same time using the same process, so their characteristics are also the same.
UDI	ISO 15223-1, 5.7.10	**U**nique **D**evice **I**dentifier	A unique numerical or alphanumeric code assigned to a medical device, which enables a clear identification of the devices which is placed on the market and facilitates their traceability.
	ISO 15223-1, 5.1.1 ISO 7000-3082	Manufacturer	It indicates the name, address and contact information of the manufacturer.
	ISO 15223-1, 5.7.3 IEC 60417-5664	Patient identification	Indicates the patient's name or dentification (ID).
31	ISO 15223-1, 5.7.6 IEC 60417-5662	Date of implantation	It indicates the date (day) of the surgery/the implantation: year-month-day.

	ISO 15223-1, 5.7.5 ISO 7001 PI PF 044	Health care provider centre and doctor	Healthcare facility/provider, which provides the name and address of the healthcare facility/provider performing the implantation, as well as the name of the physician providing the care.
	ISO 15223-1, 5.7.4 ISO 7000-3705	Patient information website	It provides the address of the website where the patient can find additional information about the medical device.

Explanation of abbreviations

MDR	**M**edical **D**evice **R**egulation (EU) 2017/745 Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices
IC	**I**mplant **C**ard
MD	**M**edical **D**evice
LOT	LOT or batch number
UDI	**U**nique **D**evice **I**dentifier
ISO	**I**nternational **O**rganization for **S**tandardization
IEC	**I**nternational **E**lectrotechnical **C**ommission
PI PF	**P**ublic **I**nformation **P**ublic **F**acilities

Reference:

- Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices: Chapter II., Article 18 - Implant card and information to be supplied to the patient with an implanted device
- MDCG 2019-8 v2 Guidance document Implant Card relating to the application of Article 18 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
- MDCG 2021-11 Guidance on Implant Card – 'Device types'
- https://health.ec.europa.eu/system/files/2021-11/md_implany-cards_factsheet_en_0.pdf
- www.team-nb.org/wp-content/uploads/2021/07/Team-NB-PositionPaper-ImplantCard-202107020.pdf
- MDCG 2019-9 Rev.1 Summary of safety and clinical performance, A guide for manufacturers and notified bodies