MDR LABELLING AND IFU REQUIREMENTS – A Notified Body PERSPECTIVE

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11th December 2024

DISCLAIMER

What is presented today is based on our current knowledge and interpretation of the MDR and the latest available MDCG guidance.

Agenda

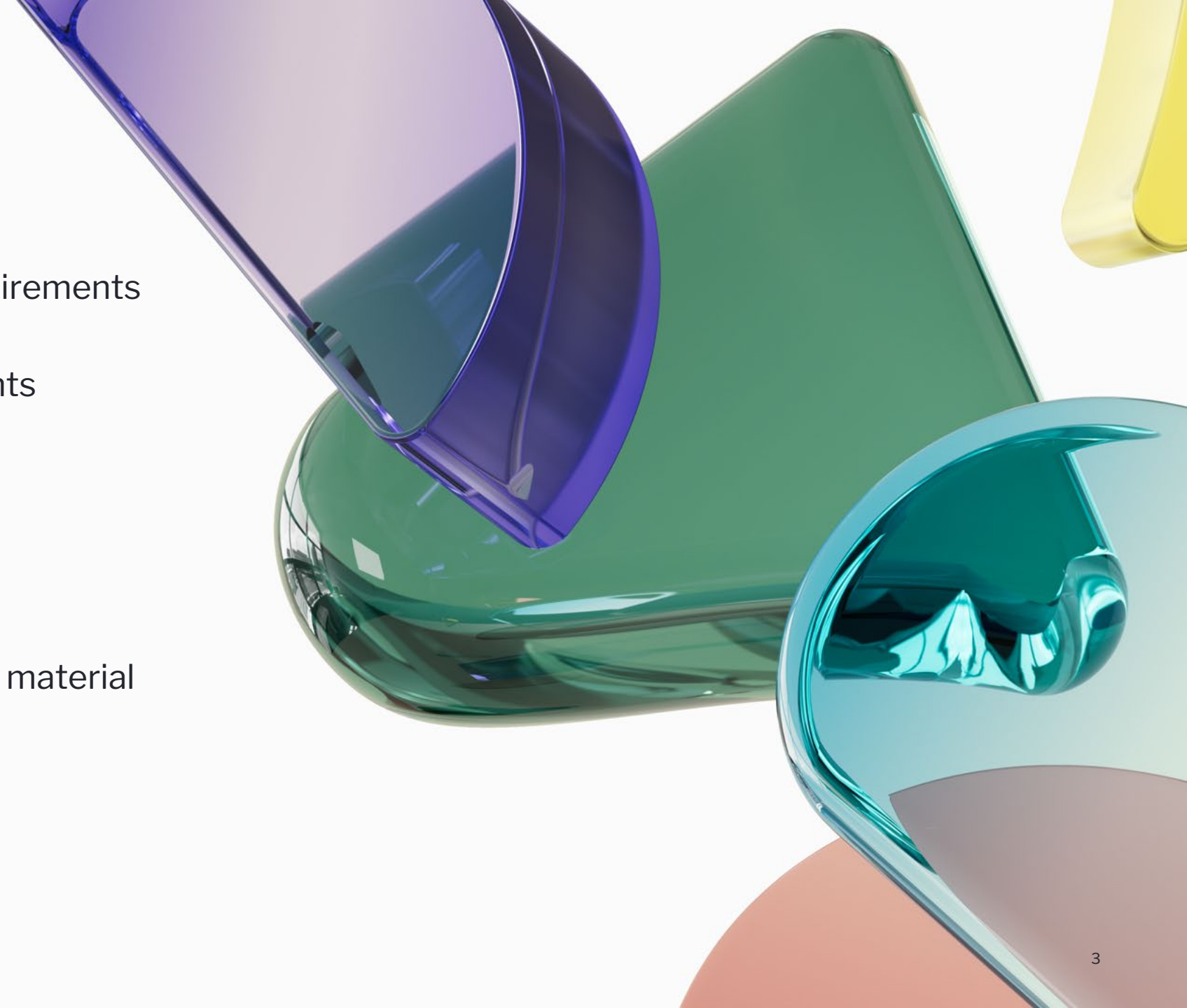
01 Navigating Regulatory requirements

02 UKCA Labelling requirements

03 Implant Cards

04 eIFU

05 Promotional and marketing material



Navigating regulatory requirements

Relevant areas of the MDR

- Annex I CHAPTER III REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE

  23.1. General requirements regarding the information supplied by the manufacturer

  23.2. Information on the label

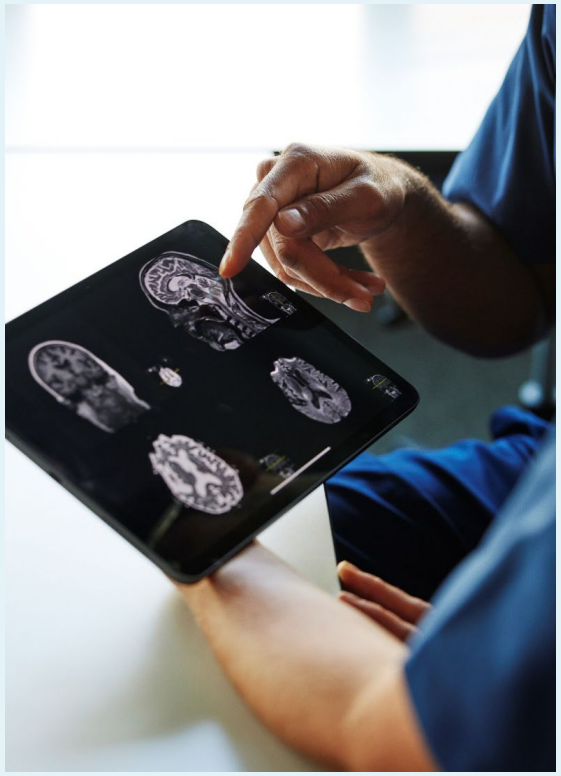
  23.3 Information on the packaging which maintains the sterile condition of a device

  23.4. Information in the instructions for use

- Annex II TECHNICAL DOCUMENTATION

  2. Information Supplied by the Manufacturer

  - Article 7 Claims
  - Article 10(11) General obligations of manufacturers
  - Article 18 Implant card and information to be supplied to the patient with an implanted device
  - Article 20 (5) CE marking of conformity



Navigating regulatory requirements

Relevant Standards, Guidance and other regulations

ISO 15223-1:2021

Symbols to be used on labelling

Represents state of the art for the Medical Device Directives and Regulation.

ISO 20417:2021

Information to be supplied by the manufacturer

General requirements for identification and labels on:

- medical device or accessory
- packaging
- marking of a medical device or accessory
- accompanying information

IEC 62366-1

IFU must be developed following a usability engineering process following 62366-1.

IEC 60601-1

specifies the contents that instructions for use of medical electrical equipment must contain.

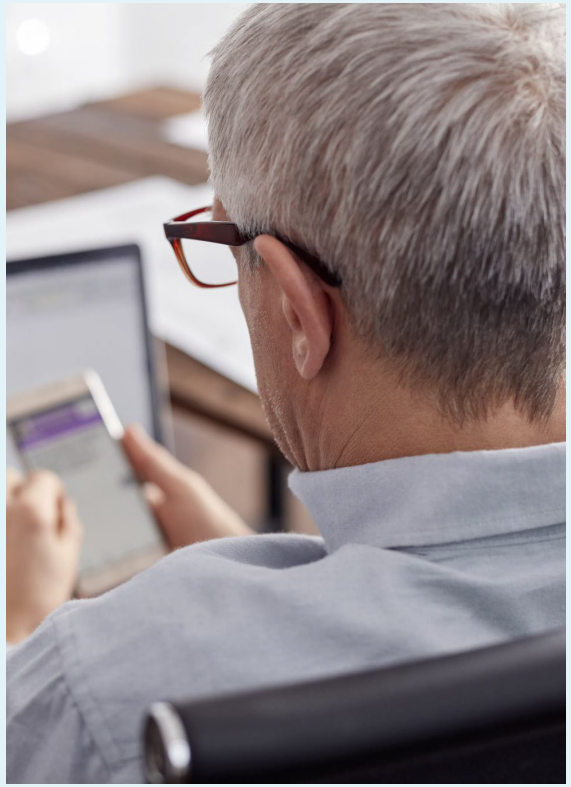
MDCG 2019-8 v2

Implant Cards and the application of Article 18

(EU) eIFU 2021/2226

electronic instructions for use of medical devices.

Other device specific standards



Navigating regulatory requirements

General Best Practice Guidance

Alignment between documentation

Key information within the IFU, such as Intended Purpose, Indications, Contra-indications, Intended patient population, Intended Users should all align with other documentation such as:

The Clinical Evaluation Report (CER),

Risk Management and

Summary of Safety and Performance (SSCP).

Be consistent in applying labelling across all documentation e.g. either MR unsafe or MR conditional

Traceability (e.g. Annex IX 2.2)

Consistent references/naming of documents and well organised documents

Navigating regulatory requirements

General Best Practice Guidance

- Remember to **include any specialist training *the user may require as per* GSPR 23.4 (j)**
- If an area does not apply to the device such as 23.4 (k) – Calibration, ensure this clearly states ‘not applicable’ in the GSPR checklist
- Clarify what, if any, analytical testing has been completed to determine the qualitative and quantitative information on the materials and substances to which patients can be exposed (NOTE: this may include leachables/extractables or other chemical breakdown products emanating from the devices over their intended lifetime).
- Consider as well Procedures/Work instructions and Alignment between documentation as CER, IFU, Risk Management,…..

Navigating regulatory requirements

General Best Practice Guidance

GSPR 23.1 (d)

There are exceptional cases where an IFU is not required for class I and class IIa devices. Consideration against Chapter I Article 2 (14), eIFU 2021/2226, etc.

GSPR 23.4 (u)

The manufacturers need to be careful in adding quantitative and qualitative information on the materials and substances to which patients can be exposed to the IFU and be consistent on those materials with their technical documentation.

GSPR 23.4 (d)

EUDAMED is not yet up and running therefore the SSCP needs to be provided another way – i.e., on the website.

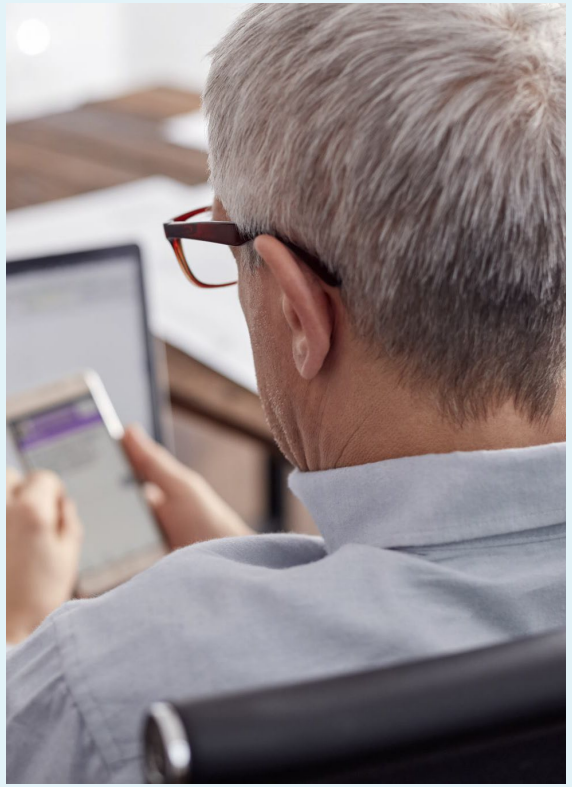
GSPR 23.4

If the device is associated with part of a system e.g. leads that are part of a pacemaker system - all information requested by GSPR 23.4 needs to be present on the leads IFU and not referenced to the pacemaker IFU.

GSPR 23.4 (b)

For devices that incorporate electronic programmable systems (including software, or software that are devices in themselves) the minimum requirements concerning hardware, IT networks characteristics and IT security measures necessary to run the software as intended must be given.

Labels, IFU and testing is all consistent.



UKCA
Labelling principles

Placing a device on the GB Market

Conformity assessment as per EU legislations (Directives, Regulations)

Directives

Conformity assessment as per EU MDD/AIMDD/IVDD

Class Is
Class Im
Class IIa
Class IIb
Class IIb implantable WET

- Upload Article 120 extension confirmation with MHRA
- UKRP appointed if required
- Conditions under 2023/607 are met
- PMS requirements as per draft SI statutory instrument coming into force mid 2024

Products can be placed on the market until 30th June 2028

Class IIb implantable non WET
Class III
AIMD

- Upload Article 120 extension confirmation with MHRA
- UKRP appointed if required
- Conditions under 2023/607 are met
- PMS requirements as per draft SI statutory instrument coming into force mid 2024*

Products can be placed on the market until 31st December 2027

List A
List B
Self Test

- UKRP appointed if required
- PMS requirements as per draft SI statutory instrument coming into force mid 2024*

Products can be placed on the market until 26th May 2030 or until they expire whichever is sooner

Placing a device on the GB Market

Conformity assessment as per EU legislations (Directives, Regulations)

Regulations

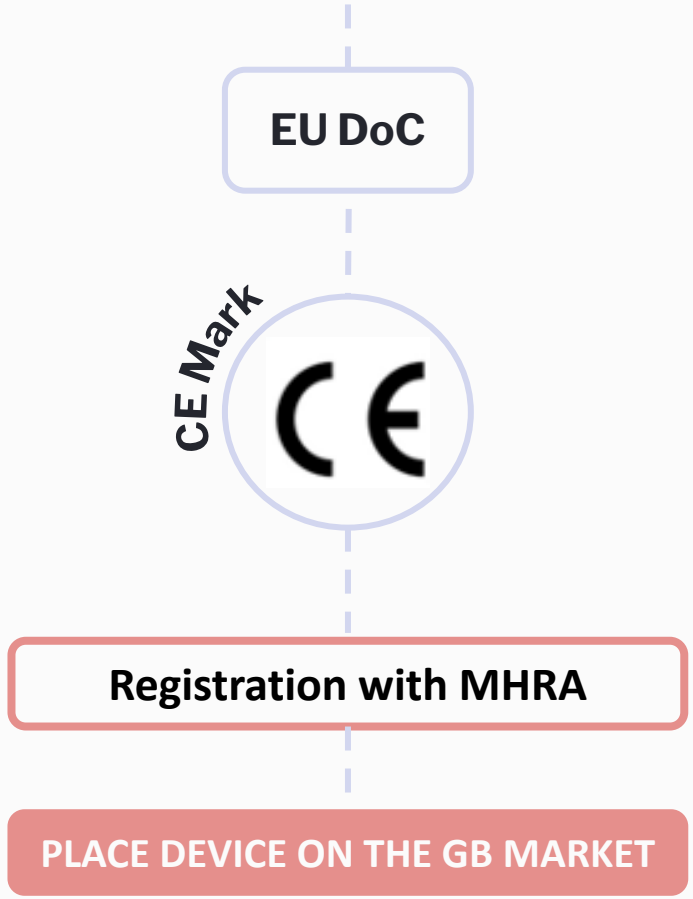
Conformity assessment as per EU MDR/IVDR

- UKRP appointed if required
- PMS requirements as per draft SI statutory instrument coming into force mid 2024*

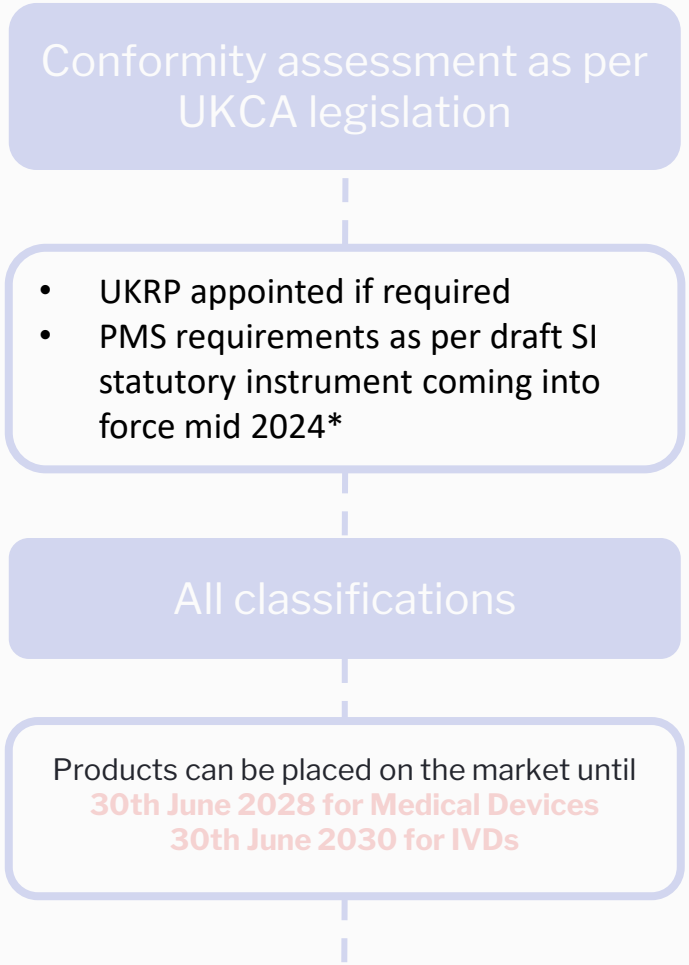
All classifications

Products can be placed on the market until
30th June 2028 for Medical Devices
30th June 2030 for IVDs

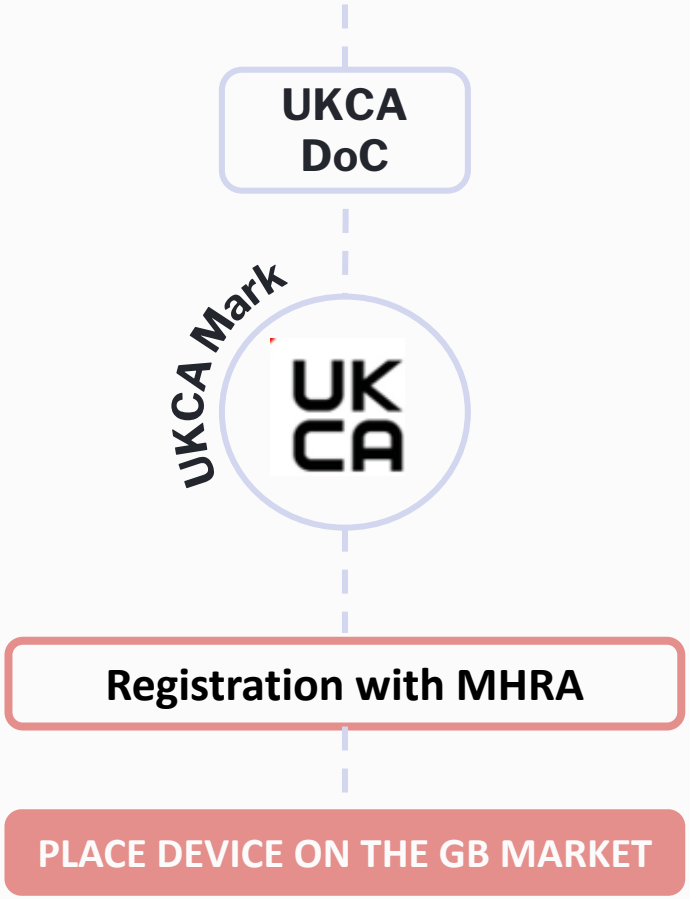
Placing a device on the GB Market



Placing a device on the GB Market

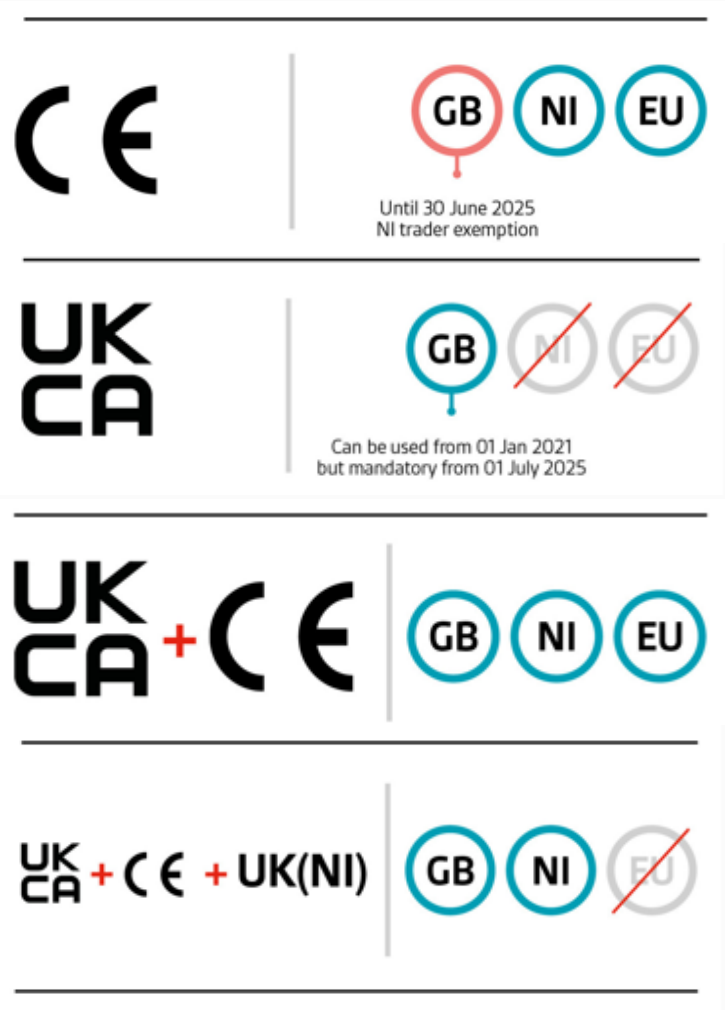


Placing a device on the GB Market



Placing a device on the GB Market

Labelling Principles



Devices placed on GB market based on EC certification / CE marking

- UKCA mark **not** to be used
- Manufacturers outside UK must appoint UKRP, but not mandatory to identify UKRP on labelling

Devices placed on GB market based on UKCA certification/UKCA mark

- **UKCA mark** must be used (some exceptions for e.g. Custom made devices)
- Manufacturers outside UK must appoint UKRP, and **identify UKRP** on either labels or IFU

The UKAB number is to be included in case a UKAB has been involved in the conformity assessment

UK CA 0000

Placing a device on the GB Market

Labelling Principles

UKCA mark placement

The device or its sterile pack, where practical and appropriate

AND

Any sales packaging for the device

AND

The instructions for use for the device

The UK Regulations provide that **a device or its sterile pack** bear the UKCA marking **where practical and appropriate**.

They also provide that a UKCA marking must be affixed to **any sales packaging for the device AND the instructions for use** for the device.

The same principles of the **EU Directives** can be applied to UKCA.

Article 17

CE marking

1. Devices, other than devices which are custom-made or intended for clinical investigations, considered to meet the essential requirements referred to in Article 3 must bear the CE marking of conformity when they are placed on the market.

2. The CE marking of conformity, as shown in Annex XII, must appear in a visible, legible and indelible form on the device or its sterile pack, where practicable and appropriate, and on the instructions for use. Where applicable, the CE marking must also appear on the sales packaging.

It shall be accompanied by the identification number of the notified body responsible for implementation of the procedures set out in Annexes II, IV, V and VI.

On any device to which the UKCA marking is affixed, the details of the UK Responsible Person should be provided, in accordance with the requirements laid out in the regulations.

For AIMD, that is on the sales packaging.
For GMD and IVD, that is on either the label, or the outer packaging or the IFU.

Note: If the UKCA mark is on the device itself, it is not a necessity that the UKRP information should also be on the device- this can be recorded on other labelling.

UKRP placement

Product labelling OR Outer packaging OR IFU

Implant cards

Implant cards

Regulatory requirements and guidance

MDCG 2019-8 v2 – Guidance document
Implant Card relating to the application of Article 18

July 2019 - version 1 published

Document endorsed by MDCG (composed of representatives of all Member States and chaired by a representative of the European Commission)

March 2020 - version 2 published

New: UDI symbol, UDI-DI required

Article 18

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

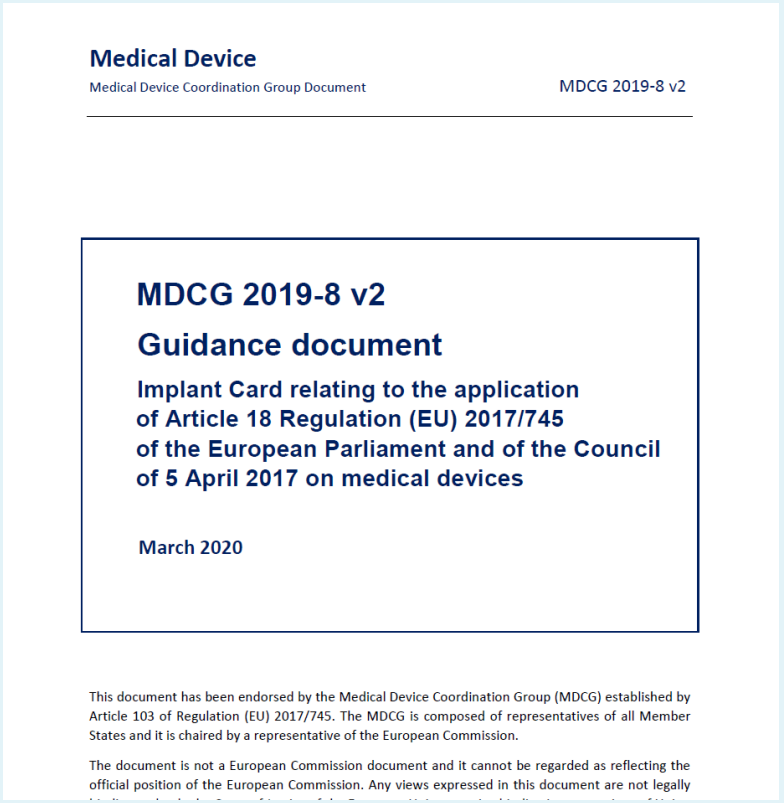
1. The manufacturer of an implantable device shall provide together with the device the following:

(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.


Medical Device

Medical Device Coordination Group Document MDCG 2019-8 v2

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

March 2020

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

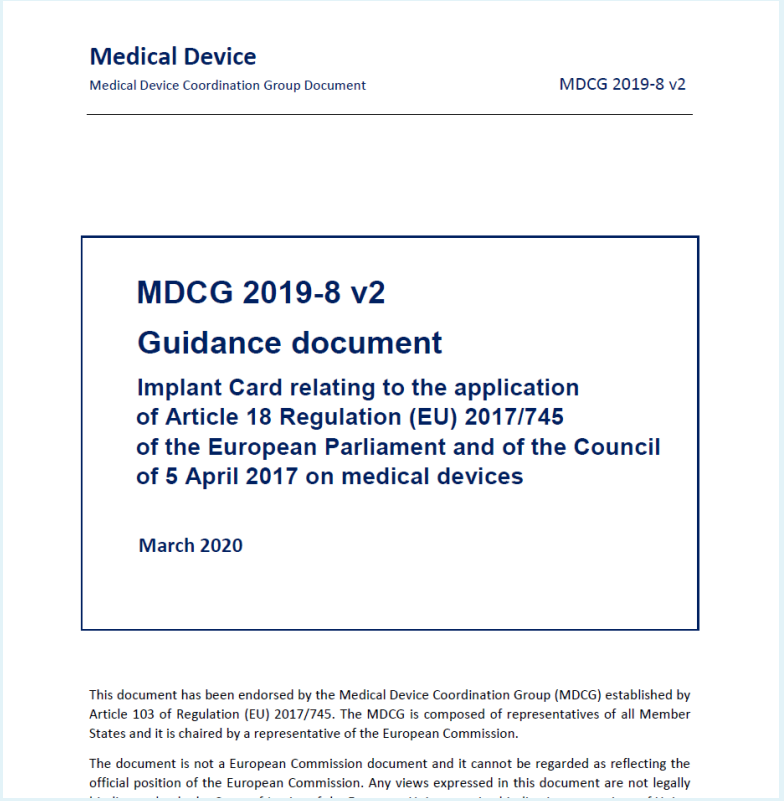
The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally

Implant cards

Regulatory requirements and guidance

1. Scope
2. Purposes of the Implant Card
3. Legal consideration on Implant Card design
4. Information to be provided by the manufacturer on the Implant Card and information to be added by the health institution
5. Use of symbols
6. Language requirements on specific fields
7. Benefits of an informative instruction leaflet
8. Implant Card for implantable systems

Annex I examples of principle designs of Implant Cards and leaflets



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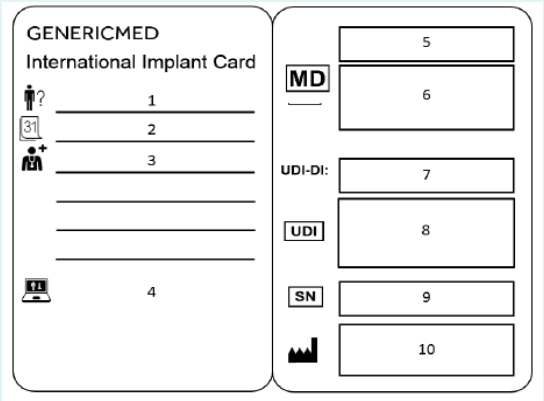
Implant cards

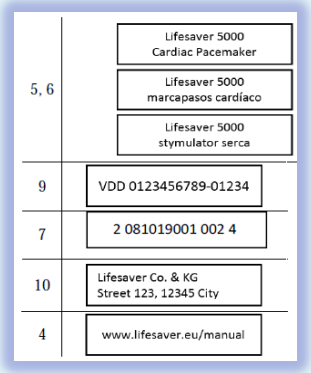
Regulatory requirements and guidance

Art 18.1 (a) information on implant card:

- Option 1: Art 18.1 (a) information is printed on the Implant card itself when provided with the device.

- Option 2: Alternatively this information may be on stickers/labels placed on the Implant card by the healthcare institution.





Implant cards

Regulatory requirements and guidance

Art 18.1 (a) information on implant card:

1. Device Name

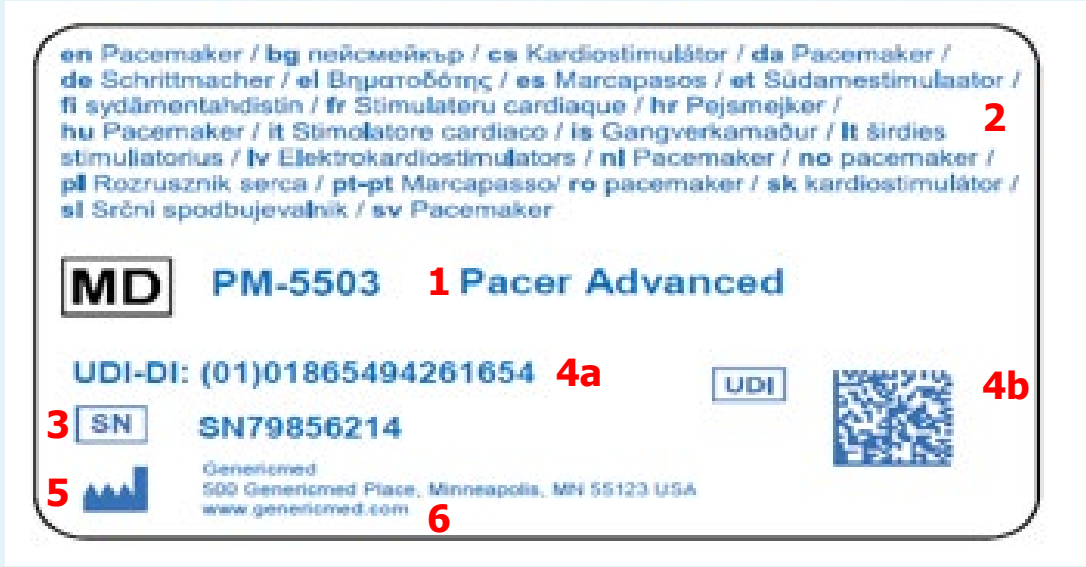
2. Device Type - Note that MDR Art. 18 text uses term "device model"

3. Serial Number OR **Lot Number** OR **Batch Number**
Any one of these is acceptable

4. UDI in AIDC format and **UDI-DI** in HRI format
(a) HRI – human readable interpretation
(b) AIDC - Automatic identification and data capture format (e.g. linear or 2D-Barcodes)

5. Name and address of the manufacturer

6. Website of the manufacturer



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;

Implant cards

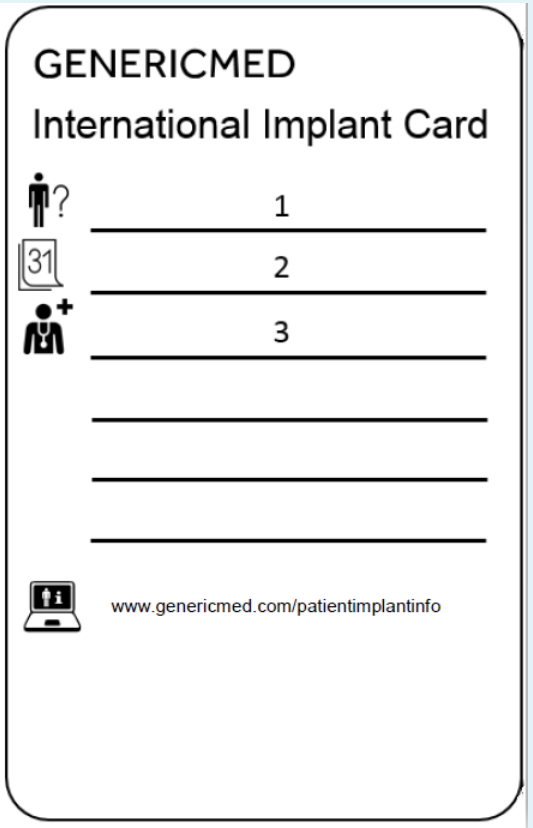
Regulatory requirements and guidance

Art 18.1 (a) information on implant card:

- The Implant Card (IC) should contain 3 specified blank fields to be filled in by the healthcare institution.

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

- Member states should not require additional information (beyond these 3 blank fields) to be added to the IC by the healthcare institution.



Implant cards

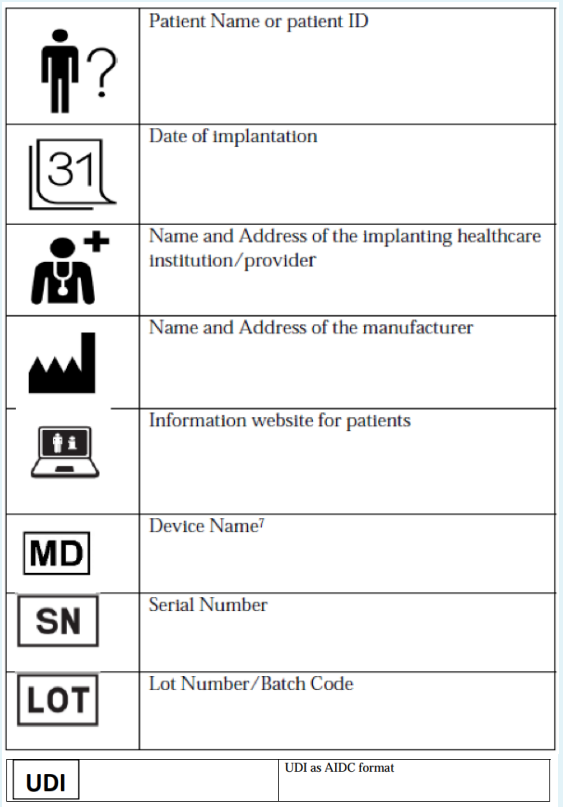
Regulatory requirements and guidance

Explanation of symbols on the IC should be provided in an informative instruction leaflet or on the back of the IC

Symbols for device name, patient information website and UDI have been validated by users according to the ISO 15223-2 process.

In the ISO context, the 'MD' symbol is used to identify that the product in question is a medical device. On the IC, this symbol is used to indicate the device name.

Please note: The UDI and UDI-DI must be on the implant card. 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.



Implant cards

Regulatory requirements and guidance

Informative Instruction Leaflet

It is recommended that manufacturers provide an informative instruction leaflet with the IC

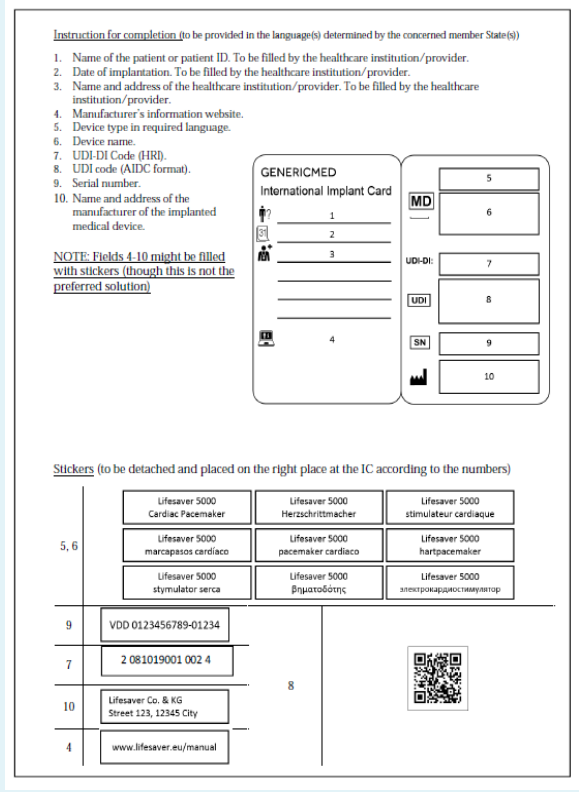
Purpose:

Instructions on how to complete the IC

To explain the symbols used

Ergonomic usability validation:

Manufacturer should validate that instructions are sufficient to enable the healthcare professional complete the IC correctly



Instruction for completion (to be provided in the language(s) determined by the concerned member State(s))

1. Name of the patient or patient ID. To be filled by the healthcare institution/provider.
2. Date of implantation. To be filled by the healthcare institution/provider.
3. Name and address of the healthcare institution/provider. To be filled by the healthcare institution/provider.
4. Manufacturer's information website.
5. Device type in required language.
6. Device name.
7. UDI-DI Code (HRI).
8. UDI code (AIDC format).
9. Serial number.
10. Name and address of the manufacturer of the implanted medical device.

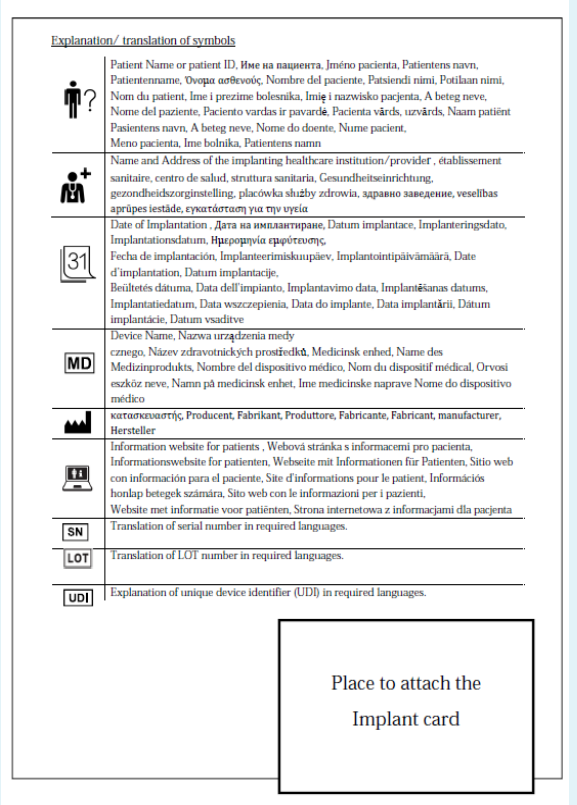
NOTE: Fields 4-10 might be filled with stickers (though this is not the preferred solution)

GENERICMED
International Implant Card

1
2
3
4
5
6
7
8
9
10

Stickers (to be detached and placed on the right place at the IC according to the numbers)

5, 6	Lifesaver 5000 Cardiac Pacemaker	Lifesaver 5000 Herzschrittmacher	Lifesaver 5000 stimulateur cardiaque
	Lifesaver 5000 marcapasos cardíaco	Lifesaver 5000 pacemaker cardiaco	Lifesaver 5000 hartpacemaker
	Lifesaver 5000 stymulator serca	Lifesaver 5000 βηματοδότης	Lifesaver 5000 электрокардиостимулятор
9	VDD 0123456789-01234		
7	2 081019001 002 4		8
10	Lifesaver Co. & KG Street 123, 12345 City		
4	www.lifesaver.eu/manual		



Explanation/ translation of symbols

	Patient Name or patient ID, Име на пациента, Jméno pacienta, Patientens navn, Patientenname, Όνομα ασθενούς, Nombre del paciente, Patsiendi nimi, Potilaan nimi, Nom du patient, Ime i prezime bolesnika, Imię i nazwisko pacjenta, A beteg neve, Nome del paziente, Paciento vardas ir pavardė, Pacienta vārds, uzvārds, Naam patiënt Pasientens navn, A beteg neve, Nome do doente, Nume pacient, Meno pacienta, Ime bolnika, Patientens namn
	Name and Address of the implanting healthcare institution/provider , établissement sanitaire, centro de salud, struttura sanitaria, Gesundheitseinrichtung, gezondheidszorginstelling, placówka służby zdrowia, здравно заведение, veselības aprūpes iestāde, εγκατάσταση για την υγεία
31	Date of Implantation , Дата на имплантиране, Datum implantace, Implanteringsdato, Implantationsdatum, Ημερομηνία εμφύτευσης, Fecha de implantación, Implanteerimiskuupäev, Implantointipäivämäärä, Date d'implantation, Datum implantacije, Beültetés dátuma, Data dell'impianto, Implantavimo data, Implantēšanas datums, Implantatiedatum, Data wszczepienia, Data do implante, Data implantării, Dátum implantácie, Datum vsaditve
MD	Device Name, Nazwa urządzenia medycznego, Název zdravotnických prostředků, Medicinsk enhed, Name des Medizinprodukts, Nombre del dispositivo médico, Nom du dispositif médical, Orvosi eszköz neve, Namn på medicinsk enhet, Ime medicinske naprave Nome do dispositivo médico
	κατασκευαστής, Producent, Fabrikant, Produttore, Fabricante, Fabricant, manufacturer, Hersteller
	Information website for patients , Webová stránka s informacemi pro pacienta, Informationswebsite for patienten, Webseite mit Informationen für Patienten, Sitio web con información para el paciente, Site d'informations pour le patient, Információs honlap betegek számára, Sito web con le informazioni per i pazienti, Website met informatie voor patiënten, Strona internetowa z informacjami dla pacjenta
SN	Translation of serial number in required languages.
LOT	Translation of LOT number in required languages.
UDI	Explanation of unique device identifier (UDI) in required languages.

Place to attach the Implant card

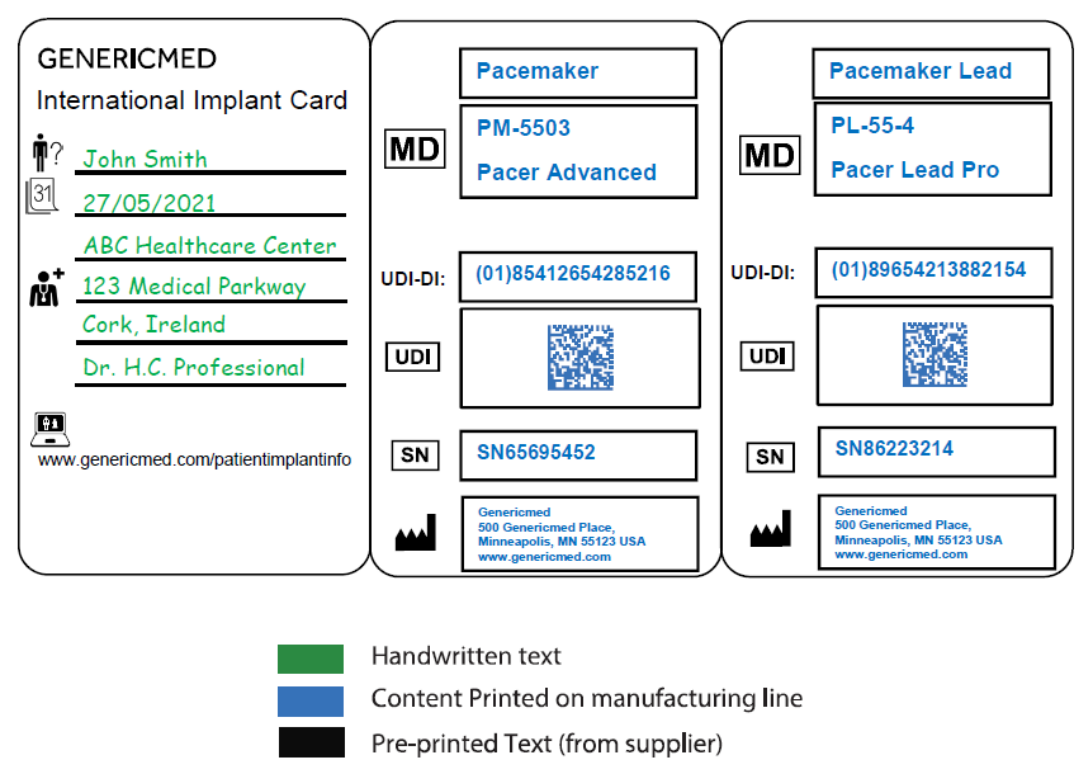
Implant cards

Regulatory requirements and guidance

System Implant Card

- If an implantable device contains implantable components which 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

- Example: To be able to represent medical device systems in one IC, the IC shall be available in collapsible form with several blank “pages” available for multiple different components



Implant cards

Regulatory requirements and guidance

System Best Practice for complying to the implant card requirements Card

- Provide information on the **text size** (Section 4 of MDCG 2019-8)
- Provide the **evidence of a readability** assessment to ensure the information supplied is understood by **lay person**, this may include **usability testing**. (Article 18)
- The **patient-oriented website/navigation** should be available in the **languages of the member states** to support compliance with Article 18 (2)
- Device Exemptions: **Not all devices require an implant card**. Check Article 18(3) list of **device exemptions**. Manufacturer should justify if they consider their device exempt. Note: Team-NB has published a position paper proposing a risk based approach to device exemptions.
- MDCG 2019-8 guidance is an official EU document **Justification must be given if this guidance document was not used** to support the conformity assessment. Annex VII, 4.5.1

eIFU – (EU) 2021/2226

Navigating regulatory requirements

(EU) 2021/2226 eIFU regulation

Within scope of eIFU 2021/2226:

Conditions under which eIFUs may be provided instead of paper IFUs for certain types of devices

Conditions under which eIFUs (including on websites) may be provided in addition to paper IFUs

Not within scope of eIFU 2021/2226:

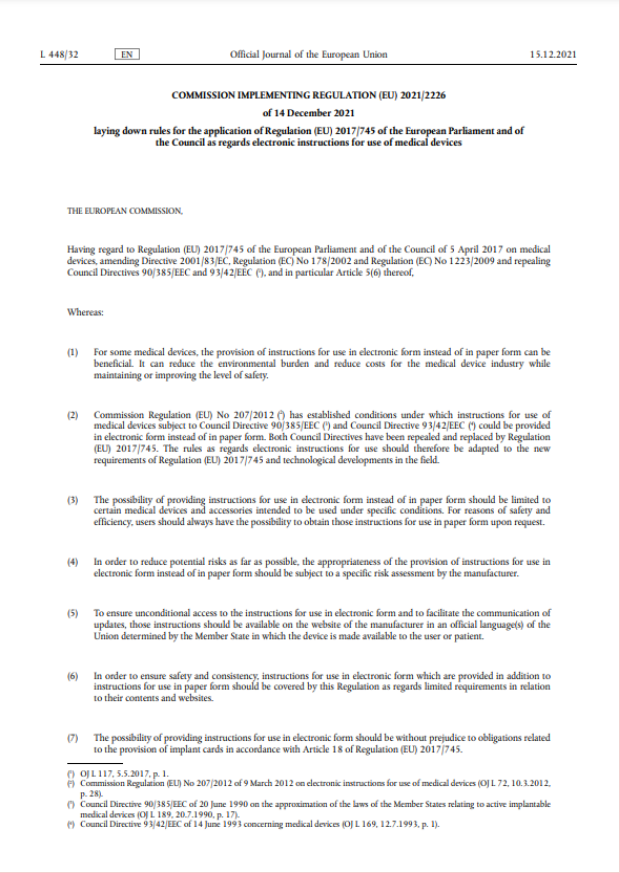
Does not cover products listed in Annex XVI of MDR (Devices without a medical purpose)

Consider GSPR 23.1f:
Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation *(i.e. (EU) 2021/2226)*

Navigating regulatory requirements

(EU) 2021/2226 eIFU regulation

Article	Changes
Article 4 – **Risk Management**	**Website compatibility** with different devices, management of different versions of the eIFU
Article 5 – **Conditions** that must be met for manufacturers to provide an eIFU	Change to the **length of duration of eIFU availability** (10 years or 15 years depending on the device type) Alerting device users to **updates or corrective actions to eIFUs** and availability of historical versions of eIFUs.
Article 6 – **Access** to eIFUs	Inclusion of **Basic UDI-DI and/or UDI-DI** to allow identification of device
Article 7 – eIFUs in **addition to paper IFU**	Website containing instructions must comply with the **GDPR regulation (EU) 2016/679** which replaces the previous directive (EU) 95/46/EC
Article 3 (3) – eIFU requirements **instead of paper from**	For **software** covered by Regulation (EU) 2017/745, manufacturers **may provide instructions for use in electronic form through the software** itself instead of in paper form.



L 448/32 EN Official Journal of the European Union 15.12.2021

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2226

of 14 December 2021

laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices

THE EUROPEAN COMMISSION,

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (1), and in particular Article 5(6) thereof,

Whereas:

(1) For some medical devices, the provision of instructions for use in electronic form instead of in paper form can be beneficial. It can reduce the environmental burden and reduce costs for the medical device industry while maintaining or improving the level of safety.

(2) Commission Regulation (EU) No 207/2012 (2) has established conditions under which instructions for use of medical devices subject to Council Directive 90/385/EEC (3) and Council Directive 93/42/EEC (4) could be provided in electronic form instead of in paper form. Both Council Directives have been repealed and replaced by Regulation (EU) 2017/745. The rules as regards electronic instructions for use should therefore be adapted to the new requirements of Regulation (EU) 2017/745 and technological developments in the field.

(3) The possibility of providing instructions for use in electronic form instead of in paper form should be limited to certain medical devices and accessories intended to be used under specific conditions. For reasons of safety and efficiency, users should always have the possibility to obtain those instructions for use in paper form upon request.

(4) In order to reduce potential risks as far as possible, the appropriateness of the provision of instructions for use in electronic form instead of in paper form should be subject to a specific risk assessment by the manufacturer.

(5) To ensure unconditional access to the instructions for use in electronic form and to facilitate the communication of updates, those instructions should be available on the website of the manufacturer in an official language(s) of the Union determined by the Member State in which the device is made available to the user or patient.

(6) In order to ensure safety and consistency, instructions for use in electronic form which are provided in addition to instructions for use in paper form should be covered by this Regulation as regards limited requirements in relation to their contents and websites.

(7) The possibility of providing instructions for use in electronic form should be without prejudice to obligations related to the provision of implant cards in accordance with Article 18 of Regulation (EU) 2017/745.

(1) OJ L 117, 5.5.2017, p. 1.
(2) Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OJ L 72, 10.3.2012, p. 28).
(3) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).
(4) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

Navigating regulatory requirements

Best practices

Summarize the mechanisms

that are in place to ensure the electronic copies of IFUs posted to the website are consistent with the paper IFUs provided in device packaging

For the IFUs that are provided in electronic form rather than paper form

provide evidence that an analysis has been performed on possible foreseeable medical emergency situations, and that this information is documented on the device or on a leaflet as per Regulation 221/2226 Article 5 (4). If a leaflet is not required, please provide a justification based upon a documented risk assessment as per Regulation 221/2226 Article 4 para. 1(g).

PMS measures – effectiveness of eIFUs

PMS data to date shows that the availability of the eIFUs has improved or maintained the level of safety when compared to providing paper IFUs

Not providing eIFUs but have a website?

The information must still comply with GSPR 23.1. Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user…. Such information may appear on the device itself, on the packaging or in the instructions for use, **and shall, if the manufacturer has a website**, **be made available and kept up to date on the website,** taking into account the following……..

IFU versus promotional and marketing material

IFU versus promotional and marketing material

Common mistakes

Article 10 (11)

General obligations of manufacturers

Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.

Controlled procedures should be in place for alignment

Article 20 (5)

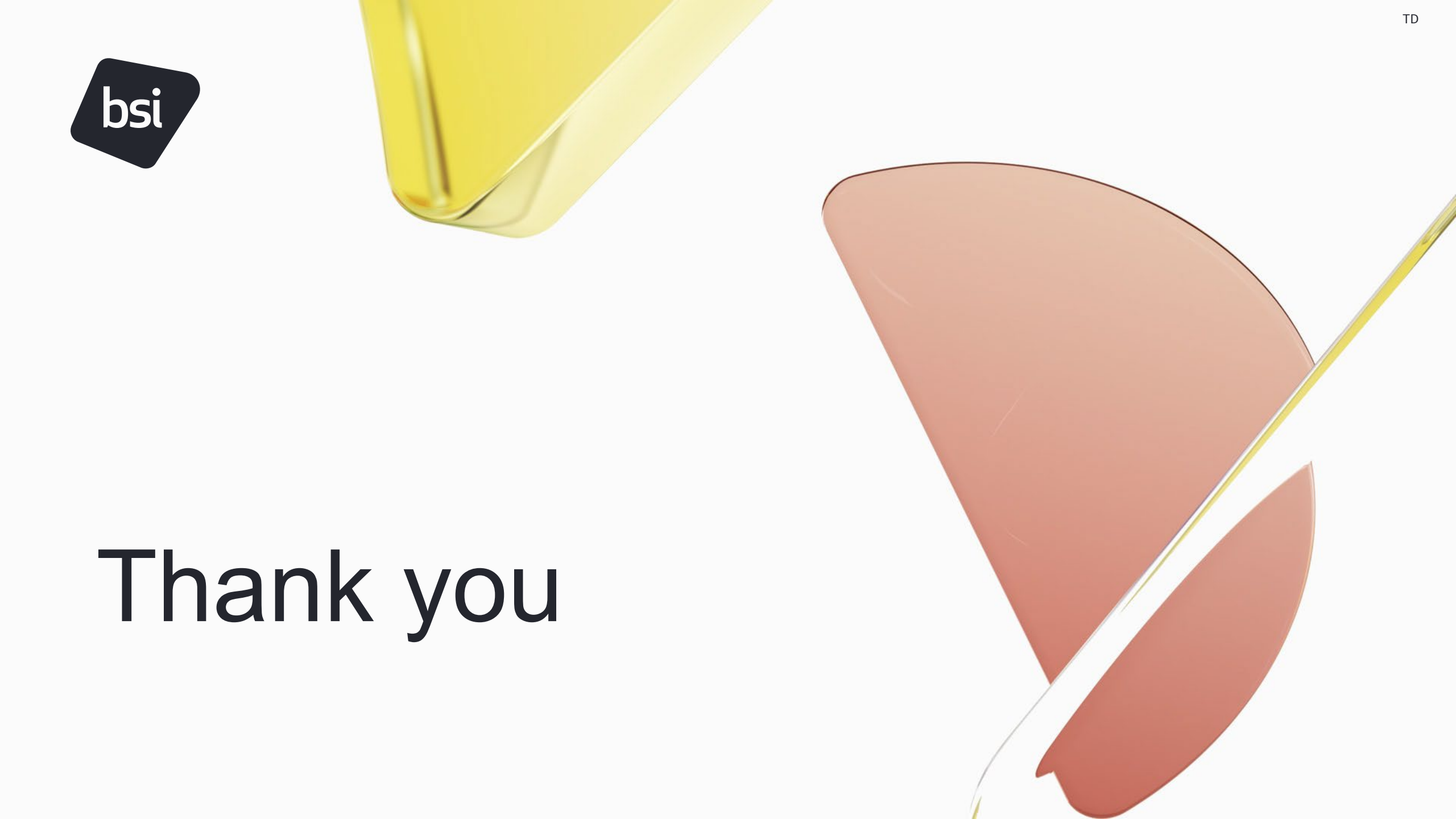
CE marking of conformity

The identification number shall also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking.

Misinterpretation of this Article – the NB will review promotional material regardless of if there is CE mark present or not.

Promotional material must adhere to Article 7

In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trade marks, pictures and ◄ figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by.....



Thank you