

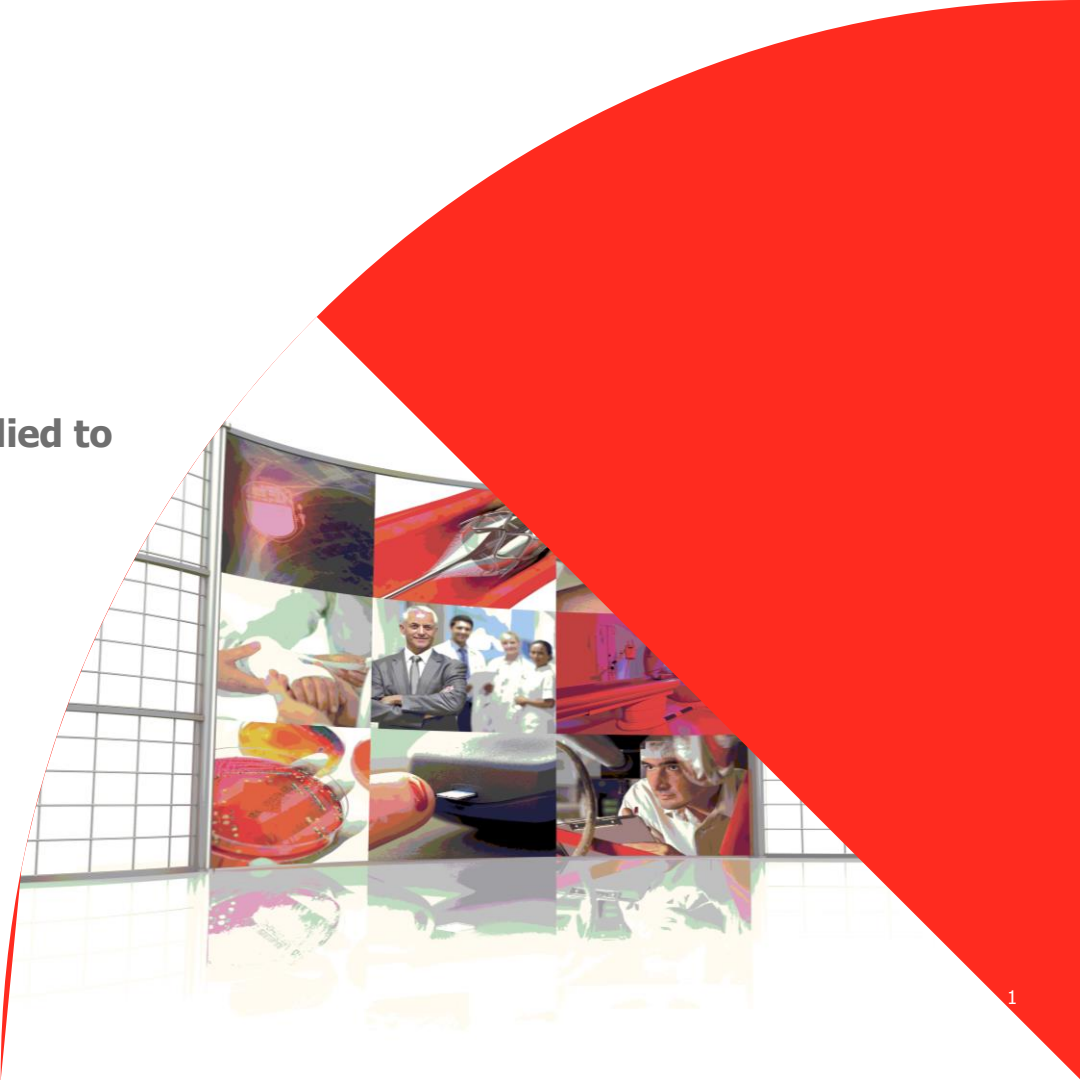
MDR Article 18

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

Kevin Madden

Training Lead & Technical Team Manager

BSI Webinar, 24 January 2019



Today's Webinar – what we will cover...

Scope: MDR Article 18 - Implant card and information to be supplied to the patient with an implanted device

1. Regulation (EU) 2017/245
2. Background to implant cards
3. Article 18 text
4. Notified Body conformity assessment
5. Implant card examples
6. Frequently asked questions
7. Your questions

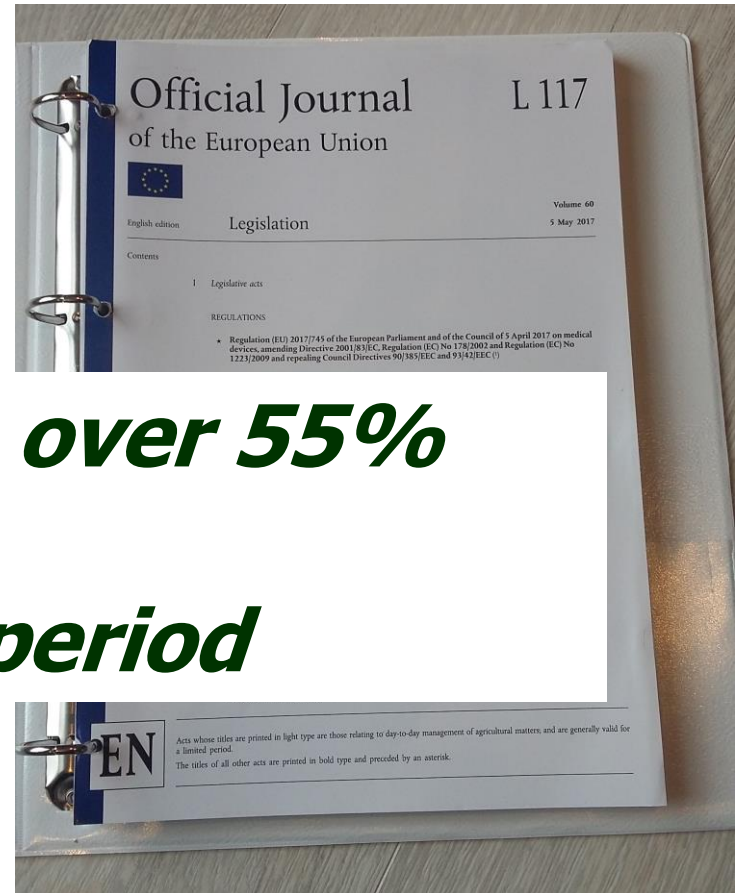
MDR: Regulation (EU) 2017/745

MDR superseded MDD+AIMDD in May 2017 with a 3 year transition period

MDR is a major

*As of today, we are over 55%
through
the transition period*

Notified Bodies
Manufacturers



Implant Cards – Background

European Commission - Fact Sheet April 2017, New EU rules to ensure safety of medical devices, ([http://europa.eu/rapid/press-release MEMO-17-848_en.htm](http://europa.eu/rapid/press-release_MEMO-17-848_en.htm)):

"What are the main benefits for patients and consumers?...

...an 'implant card' for patients containing information about implanted medical devices that will make information easily available and accessible to the particular patient"

Anticipated benefits:

- Provide information during an emergency
- Provide information or safety requirements regarding reciprocal interference
- Improve patient awareness of warnings/precautions and limitations of normal activity
- Improve data entry to implant registries (particularly to identify failed components in a revision surgery)

Purposes of the Implant Card

1. Enable the patient to identify the implanted device.

- E.g. in the event of recalls via news, the patient can check whether they are affected or they can identify the healthcare institution they have to contact (UDI to support search in Eudamed and on manufacturer website).

2. Enable patients to identify themselves as persons requiring special care with regards to security checks etc.

- E.g. a cardiac pacemaker wearer could use the implant card to prove that they are not allowed to pass through a body scanner during security checks at airports.

3. In emergency cases the implant card might be used to inform (e.g. the first responder) about special needs

- E.g. Healthcare professionals could identify that there is an active implant which might influence other diagnostic or therapeutic devices (or might be a contraindication)

Implant ID – Precedent in Germany

- Implant ID's in paper are mandatory since 01 Oct 2015 in Germany in accordance with BVMed regulation.
- Hospitals and all health facilities are obliged to provide an implant ID to their patients for active implantable devices, heart valves, non-resorbable vascular implants, stents, breast implants, joint implants (hip, knee), spinal implants).
- The Implant ID shall contain the following data:
 - Patient's full name
 - Implant specific data (Lot # or SN, device specific details)
 - Date of implantation
 - Name of the surgeon
 - Health facility/hospital



Article 18 of 123...looks fairly short & simple...

The name and address of the manufacturer of the original single-use device shall no longer appear on the label, but shall be mentioned in the instructions for use of the reprocessed device.

9. A Member State that permits reprocessing of single-use devices may maintain or introduce national provisions that restrict that the laid down in the following:

- (a) the reprocessing of single-use devices and the transfer of single-use devices to another Member state or to a third country with a view to their reprocessing;
- (b) the making available or further use of reprocessed single-use devices.

Member States shall notify the Commission and the other Member States of those national provisions. The Commission shall make such information publicly available.

10. The Commission shall by 27 May 2024 draw up a report on the operation of this Article and submit it to the European Parliament and to the Council. On the basis of that report, the Commission shall, if appropriate, make proposals for amendments to this Regulation.

Article 18
IMPLANT CARD

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.

Article 18 – Summary

In a...



1. **Manufacturers shall**

- provide device information (as listed in Article 18.1 points a-d) and update this information where appropriate
- provide a physical implant card with information listed in Article 18.1 point a

2. **Health Institutions shall**

- make device information (as listed in Article 18.1 points a-d) available to the patient
- provide the physical implant card with patients name on it to the patient

3. **Some implants don't need to meet Article 18**

- well established technology

Article 18 of 123...looks fairly short & simple...

The name and address of the original single-use device shall no longer appear on the label, but shall be mentioned in the instructions for use of the reprocessed device.

9. A Member State that permits reprocessing of single-use devices may maintain or introduce national provisions that restrict that the laid down in Article 18 and without prejudice to the following:

- (a) the reprocessing of single-use devices and the transfer of single-use devices to another Member state or to a third country with a view to their reprocessing;
- (b) the making available or further use of reprocessed single-use devices.

Member States shall notify the Commission and the other Member States of those national provisions. The Commission shall make such information publicly available.

10. The Commission shall by 27 May 2024 draw up a report on the operation of this Article and submit it to the European Parliament and to the Council. On the basis of that report, the Commission shall, if appropriate, make proposals for amendments to this Regulation.

Article 18

IMPLANT
CARD

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

straightforward?

- the following information to be supplied to the patient with the device the following:
- (a) information about the identification of the device, including the device name, identification number, lot number, the manufacturer's name, the device model, and the name of the manufacturer and the manufacturer's website;
 - (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 (a) of Section 23.4 of Annex I.

MDR Article 18 Text – Clause 1 – Manufacturers

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. (*the overall **qualitative and quantitative information on the materials and substances** to which patients can be exposed*)

MDR Article 18 Text – Clause 1 – Manufacturers

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.**

MDR Article 18 Text – Clause 2 – Health Institutions

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**.



Health Institutions

Background

The new Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Device Regulation (IVDR) entered into force on 25 May 2017. Once fully applied, they will replace the medical device, in vitro diagnostic medical device and active implantable medical device Directives.

The new regulations include obligations that health institutions will need to meet by 26 May 2020 for medical devices and 26 May 2022 for in vitro diagnostic devices. Health institutions are defined as "an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health" (Article 2(36) of the MDR). The key requirements are listed below, with more details included in Articles referenced.

Timeline



Current situation

The current EU medical device and in vitro diagnostic medical device Directives (MDD and IVDD) do not apply to devices manufactured and used only within the same health institution and on the premises of their manufacture or used on premises in the immediate vicinity without having been transferred to another legal entity (in-house use).

Therefore, under the Directives, devices manufactured and used within health institutions are not considered as having been put into service and health institutions are exempt from the obligations set out in the Directives.

Key changes set out in the MDR and IVDR



Health institution exemption

(Article 5 of MDR / IVDR)

Devices that are manufactured or modified and used within health institutions shall be considered as having been put into service.

The requirements in the MDR/IVDR shall not apply to these devices provided that the certain conditions are met, including:

- Health institutions ensure that manufacturers follow the relevant general safety and performance requirements (Annex I);
- An appropriate quality management system is established;
- The health institution justifies that the target group's specific needs cannot be met by an equivalent device on the market;
- Information is made available to competent authorities on request;
- A declaration with certain details is made publicly available;
- Reviews experience gained from clinical use of the devices and takes all necessary corrective actions.



Implant cards

(Article 18 of MDR)

Health institutions will need to provide patients with implantable devices with an implant card, which shall bear the patient's identity, as well as rapid access to certain information, including:

- The identification of the device, including the device name, serial number, lot number, the UDI, the device model, and the name, address and website of the manufacturer;
- Warnings, precautions or measures to be taken by the patient or a healthcare professional;
- The expected lifetime of the device and any necessary follow-up.



Unique Device Identification

(Article 27 of MDR / Article 24 of the IVDR)

The UDI system will allow for things like safety alerts, potential recalls, as well as surveillance tasks more generally.

For Class III implantable medical devices, health institutions will need to store and keep preferably by electronic means the UDI of the devices which they have supplied or with which they have been supplied.

Health institutions may be required to do this for other devices also.

The UDI system will have a longer phase-in time (e.g. the requirement applies for class III and implantable devices in May 2021 and class A IVDs in May 2027).

Other changes

Clinical trial / performance studies – Article 73 of MDR / Article 69 of IVDR: significant alignment with the CTR, for example introducing damage compensation and a 'Sponsor'.

Single-use devices and their reprocessing – Article 17 of MDR: may only take place where permitted by national law, but must meet certain conditions. The MHRA will consult on its current position on reprocessing.

3D printed devices – a case-by case assessment will be required to determine a product's status and classification.

Software – classification rules will change with more software requiring notified body input.

MDR Article 18 Text – Clause 3 – Exemptions

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.



Article 18 Webinar – Progress...

- ✓ Regulation (EU) 2017/245
- ✓ Background to Article 18
- ✓ Article 18 text

4. **NB conformity assessment**

5. Implant Card Examples
6. Frequently Asked Questions
7. Audience Questions

NB Conformity Assessment against Article 18

- **Is the device implantable and not an exempted implant per Art. 18 clause 3?**
 - **If so, the obligations of Article 18 are applicable.**
- **Notified bodies will check for conformity against all requirements of Article 18.**
- Example NB questions:
 - Is all Art. 18 clause 1 (a) information on the implant card?
 - Has all Art. 18 clause 1 (b, c & d) information been provided by a means that allow the patient rapid access to that information? Has the manufacturer justified their solution and demonstrated compliance?
 - Are any warnings/precautions/measures to be taken by the patient or HCP regarding reciprocal interference provided?
 - Has a quantified lifetime been provided? Has information on necessary follow-up been provided?
 - Has sufficient information been provided to ensure safe use of the device by the patient?
 - Has qualitative and quantitative information on materials/substances been provided?
 - Is the information written in way that is readily understood by a lay person? How has this been validated by the manufacturer?

NB Conformity Assessment against Article 18

- Example questions:
 - Can the patient rapidly access the Art 18 clause 1 b – d information? Has the manufacturer appropriately considered patient demographics in their solution?
 - Does the identified manufacturer website generally adhere to the concepts of the eIFU regulation (207/2012)?
 - Should there be a back up available for patients without access to internet (e.g. information pack sent out by post) or can the responsibility of the Health Institution cover ensuring the patient can access a website or provide a print out of the information if needed?
 - Has the manufacturer considered multiple devices being implanted in one surgery? It is perhaps acceptable to have multiple “peel off labels” applied (by the health institution) to one “generic implant card”. How many spaces should be available? Should guidance on this be provided to health institutions by the manufacturer?
 - Has the manufacturer considered if their implant cards (particularly for certain higher risk implants like pacemakers) be designed to be carried permanently (credit card size/shape, laminated implant cards). What is the expected “lifetime” of the implant card and has this been justified and validated?

NB Conformity Assessment against Article 18

- Example additional NB checks:
 - NB's will check that the implant card has a designated location for the health institution to record the patient identity.
 - NB's will check that IFU information aligns with implant card information (ref. SPR 23.4: *The instructions for use shall contain all of the following particulars:...(aa) information to be supplied to the patient with an implanted device in accordance with Article 18*)
 - NB's will check that implant card information aligns with risk management, clinical evaluation and other applicable technical documentation
- **The EU wide position on acceptable Article 18 solutions has not yet been fully finalised. Guidance is expected at some stage in future but it is not clear when.**
- **A variety of approaches may be possible but conformance to all applicable Article 18 requirements must be clearly demonstrated by the manufacturer.**

Article 18 Webinar – Progress...

- ✓ Regulation (EU) 2017/245
- ✓ Background to Article 18
- ✓ Article 18 text
- ✓ NB conformity assessment

5. Implant card examples

6. Frequently asked questions

7. Your questions

Example 1 – Blank implant card to write in information

Front

Acme Device Patient Implant Card
Superbz Surgical Mesh

Patient Name: _____
Implant Date: _____
Implanting Physician: _____
Physician Tel. No.: _____

Acme Device, 0086 First Street,
City, State 00086, USA
+1 800 555 5555
www.AcmeDevice.com

Back

Acme Device Patient Implant Card
Superbz Surgical Mesh

Device Name: _____
Lot No.: _____
UDI No.: _____
Product REF/Model No.: _____

Doc 12345678 Rev 0 English / 2018-09

Card contains blanks to hand-write required content per Article 18.1[a]: Device name, model, lot number, UDI

Implied but not specifically stated that the website is for accessing Patient Implant information (Article 18.1 b - d)

This is not acceptable:

- Art. 18.1 (a) info. not provided on implant card as is required
- Implant card includes English text but no translations. Does this meet Art. 18.1 requirements for member state languages?
- How is the manufacturer providing Art. 18.1 (b) – (d) info.?
- Clearly does not meet requirements

Example 2 – Generic implant card to affix peel off labels

Base implant card, a controlled document, with example labels affixed

Front

Back

Doc 12345678-EN Rev 0 / 2018-09

Acme Device

0086 First Street
City, State 00086
USA

Patient Implant Card

For additional implant information go to the below website and enter MODEL or UDI number.
Alternatively, call customer service at:
+1 800 555 5555
www.acme-device.com/implantcards

Patient name

Doctor/Hospital Information

NAME: Modular OrthoImplant Head
MODEL: XXX50-YY03 LOT: 85472745
UDI-DI: xxxxxxxxxxxxxxxx
Acme Device, 0086 First Street, City, State 00086, USA

NAME: Modular OrthoImplant Stem
MODEL: S0008 LOT: 44501012
UDI-DI: xxxxxxxxxxxxxxxx
Acme Device, 0086 First Street, City, State 00086, USA

NAME: Modular OrthoImplant Cup
MODEL: C05-PT-03 LOT: 06230909
UDI-DI: xxxxxxxxxxxxxxxx
Acme Device, 0086 First Street, City, State 00086, USA

Manufacturer website for accessing Patient Implant information with phone as alternative to obtain document (Article 18.1 [a])

Space for information to be added by hospital (patient name: Article 18.2)

Example affixed implant labels

Spaces for multiple/additional labels, perhaps if multiple implants expected in a procedure

This is better than Example 1 but there are some questions:

- The UDI number appears to be incomplete, UDI-PI has not been provided
- Has the serial number been provided? Is this the Model no.?
- Implant card includes English text but no translations. Does this meet Art. 18.1 requirements for member state languages?
- How are they providing Art. 18.1 b-d information? Have they justified their solution?

Article 18 Webinar – Progress...

- ✓ Regulation (EU) 2017/245
- ✓ Background to Article 18
- ✓ Article 18 text
- ✓ NB conformity assessment
- ✓ Implant card examples

5. Frequently asked questions

6. Your questions

Article 18 – Frequently Asked Questions

1. Do implant cards have to be provided retrospectively for devices already placed on the market?

No, Article 18 requirements apply only to devices placed on the market under Regulation (EU) 2017/245

Article 18 – Frequently Asked Questions

2. Does Article 18 force manufacturers to have a website to communicate with patients of implants?

Yes, a website is a requirement per Article 18 clause 1, paragraph 2.

Article 18 – Frequently Asked Questions

3. Is the expectation that along with the Implant card, the manufacturer also provide a patient leaflet with EVERY single implant card?

The manufacturer must justify how they are demonstrating compliance with Article 18

Per Art. 18 clause 1: *“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.”*

All Article 18 clause 1 a – d information must be provided by the manufacturer to be made available to the patient by the health institution.

Manufacturers can meet this requirement by various solutions which they must justify.

Article 18 – Frequently Asked Questions

4. Does all the information in Article 18.1 a-d have to be on the implant card or can it be supplied a different way?

Only the information per Art. 18 clause 1 (a) must be on the physical implant card. Clause 1 (b)-(d) information can be provided by other means.

Per Article 18 clause 1 final paragraph

“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.”

Point (a) states

(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;

Article 18 – Frequently Asked Questions

5. Can the information in b-d of Article 18 clause 1 be provided on a website instead of a paper copy?

Art. 18 clause 1 b-d information shall be on the manufacturers website. Also, the manufacturer must be able to justify how their solution meets Article 18 clause 1 first paragraph

"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. "*

Article 18 – Frequently Asked Questions

5. Can the information in b-d of Article 18 clause 1 be provided on a website instead of a paper copy?

Note: It is a requirement of Annex I 23.4 (aa) that the IFU contains all Article 18 clause 1 a-d information

Per SPR 23.4: *The instructions for use shall contain all of the following particulars:*

(aa) information to be supplied to the patient with an implanted device in accordance with Article 18

Article 18 – Frequently Asked Questions

6. Is it possible to identify the manufacturer website via a QR Code or should a WWW. domain be present as well?



No, it is not expected that patients would be able to access the information easily via a QR code. **The www website domain should be identified.** The patient must be able to readily understand the information and get rapid access to the information on the website.

Per Article 18 clause 1: "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."

Article 18 – Frequently Asked Questions

7. Can blank implant cards be provided to the healthcare institution and these blank cards used in conjunction with adhesive labels provided in the device packaging that contain the necessary information from Article 18,1(a)?

The manufacturer must be able to justify how this meets Article 18 clause 1, paragraph 3

“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.”

It is not expected that pre-supplied generic blank implant cards will be an acceptable Article 18 solution.

Article 18 – Frequently Asked Questions

8. Are there any GDPR privacy concerns regarding the "identity" of the patient?

Per Article 18 clause 2, only the physical implant card provided to the patient by the health institution shall bear the identity of the patient. The patient name will almost always be assigned at the point of care and the implant card is then the property of the patient.

It is the manufacturers responsibility to ensure GDPR compliance. We will not be reviewing against GDPR requirements.

Article 18 – Frequently Asked Questions

9. Which sub-sections of Annex I part 23 apply to the implant card?

Article 18 specifically refers to SPR 23.4 point (u):

"(u) in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed"

Per SPR 23.4: *The instructions for use shall contain all of the following particulars:*

(aa) information to be supplied to the patient with an implanted device in accordance with Article 18

Article 18 – Frequently Asked Questions

10. Do the requirements for implant cards apply to resorbable implants?

The MDR definition for “Implant” include resorbable devices. All implants not on the exemption list must have an implant card. Article 18 indicates the devices that are exempt from the requirement for an Implant Card.

11. Should the implant card describe the rate of absorption for absorbable implants?

Article 18 does not specifically call out “rate of absorption”. The manufacturer must determine what information is required under point 1c and 1d of Article 18.

Article 18 – Frequently Asked Questions

12. Do we need to put both the UDI-DI and UDI-PI on the implant card? What UDI needs to be exactly on the implant card?

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

Per Article 18 clause 1 (a): *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;*

Therefore the UDI is required on the implant card.

Per Article 27, 1(a) and Annex VI 3.3, **the UDI comprises both UDI-DI and UDI-PI.**

Article 18 – Frequently Asked Questions (final one...)

13. Does the UDI on the implant card need to be human readable, or machine readable, or both?

Human readable is required as the UDI is defined as being comprised of human readable characters.

Per Annex VI, Part C.1: Unique Device Identifier ('UDI') **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 UDI-DI and the UDI-PI.

Article 18 Webinar – Progress...

- ✓ Regulation (EU) 2017/245
- ✓ Background to Article 18
- ✓ Article 18 text
- ✓ NB conformity assessment
- ✓ Implant card examples
- ✓ Frequently asked questions

5. Your questions

Your Questions?



Article 18 – In A Nutshell...

1. **Manufacturers shall**

- provide device information (as listed in Article 18.1 points a-d) and update this information where appropriate
- provide a physical implant card with information listed in Article 18.1 point a

2. **Health Institutions shall**

- make device information (as listed in Article 18.1 points a-d) available to the patient
- provide the physical implant card with patients name on it to the patient

3. **Some implants don't need to meet Article 18**

- well established technology

In a...



Article 18 – Final Thoughts...

- **The EU wide position on acceptable Article 18 solutions has not been fully finalised. Commission guidance is expected but not in the short term.**
- **A variety of approaches may be possible but conformance to all applicable Article 18 requirements must be clearly demonstrated by the manufacturer.**
- **The suitability of Article 18 solutions should consider specific device / HCP / patient factors and should be risk assessed and justified by the manufacturer**
- **MDR Article 18...a short but demanding little article 😊**



Thank you all for listening....

Kevin Madden

Training Lead & Technical Team Manager,
Orthopaedic & Dental Team

BSI Medical Devices

kevin.madden@bsigroup.com

www.bsigroup.com/en-IE/medical-devices

The screenshot shows the BSI website's 'Medical Devices' section. At the top, the BSI logo is followed by the tagline '...making excellence a habit.' and a phone number '+353 1 210 1711'. A navigation bar includes 'Home', 'Standards e.g. ISO 9001', 'Our services', 'Industry sectors', and 'About BSI', along with a search bar. Below this is a sub-navigation bar for 'Medical Devices' with links to 'Medical Devices', 'Market access', 'Services', 'Technologies', 'Resources', and 'News'. The main content area features a 'Resources' heading and a sub-heading 'Download our latest materials to learn more about the services and benefits we can provide.' To the right of the text is an image of a stack of papers. On the left side of the page, there are social media icons for LinkedIn, Twitter, Facebook, Google+, and Email.

Learn more by using our medical device resource centre

As a global industry leader, we are committed to sharing best practice by providing easy access to information that helps our customers stay up to date on the latest changes to standards, current industry trends, as well as forward-looking resources that can help you prepare for what lies ahead.

Our resources cover everything from the services we provide including the medical devices we support to customer case studies and links to key medical device professional and trade associations.

Contact us

Find out how BSI can support you in achieving excellence with Standards, Certification and Assessment.

[Send us an email](#)

[Talk to us](#)

bsi.

...making excellence a habit.™