The European Association
Medical Devices - Notified Bodies

Team-NB Position Paper

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Team-NB Position Paper on a risk-based approach for medical devices exempted from an implant card and information to be supplied to the patient with an implanted device per Article 18.3

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1. Scope

This document is the aligned position of the Team-NB members on the device types exempted from the requirements in Regulation (EU) 2017/745 (MDR)[1], Article 18.3 to provide an implant card and to supply certain information to the patient. This position paper proposes a risk-based approach to determine which devices do not need an implant card to fulfil the risk mitigation requirements in MDR, Annex I, Chapter I, 4. (c).

Custom-made devices are required to conform with the general safety and performance requirements set out in Annex I and are in scope of this position paper.

Article 18 requirements apply to all implants not included in the exemption list of Article 18.3. This list can only be changed by the adoption of delegated acts in accordance with Article 115. This position paper is based on the current list of exempted devices at the time of the publication of this paper.

Although currently including the same list of exempted devices the Articles 52.4 (conformity assessment procedures) and 61.6 (clinical evaluation) are not in scope of this position paper.

This is a position paper; manufacturers should familiarise themselves with the legislative and regulatory requirements and, if necessary, seek professional advice.

It is the responsibility of manufacturers to understand and comply with the current version of the regulatory requirements.

2. Introduction

The MDR in Article 18 includes specific requirements for implantable medical devices, independent of the risk class, which attributes to the specific clinical risks of these devices.

In the publication of the MDR in the Official Journal of the European Union it is stated in recital 39: 'Patients who are implanted with a device should be given clear and easily accessible essential information allowing the implanted device to be identified and other relevant information about the device, including any necessary health risk warnings or precautions to be taken, for example indications as to whether or not it is compatible with certain diagnostic devices or with scanners used for security controls.'[2]

However, the Regulation also provides a list of certain implantable device types which are exempted from the requirements of Article 18. These implants are listed in Article 18.3: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.

While these devices are excluded from the statutory requirement to provide an implant card (Art. 18.1 a) and patient information materials (Art. 18.1 b, c, d), manufacturers might still consider using a risk-based approach providing an implant card and patient information materials for these devices, as part of their overall risk management.

3. Legal texts

3.1 Exemptions of the requirement to supply an implant card under the MDR

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.

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.

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.

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.

MDCG Guidance Documents concerning information on implantable devices supplied to patients

MDCG 2019-8[3]

Purposes of the Implant Card

The aim of introducing an IC has been to achieve three main objectives:

1. Enable the patient to identify the implanted devices and to get access to other information related to the implanted device (e.g. via EUDAMED, and other websites).

2. Enable patients to identify themselves as persons requiring special care in relevant situations e. g. security checks.

3. Enabling e.g. emergency clinical staff or first responder to be informed about special care/needs for relevant patients in case of emergency situations.

MDCG 2019-9[4]

[…]

Relevant SSCP information for patients

The MDR indicates that patients are also intended recipients of the information in the SSCP, "if relevant. Devices for which information will be especially relevant for patients include:

• implantable devices for which patients will be given implant cards, and

• class III devices that are intended to be used directly by patients.

For these devices, a part of the SSCP specifically intended for patients should be provided.

3.2 Considerations on the list of exempted devices

The reasoning for exempting certain devices is not stated in the MDR. Due to the applicability of the MDR to a broad field of medical disciplines (e.g., orthopaedics, neurosurgery, dentistry) the use of general terminology for the description of implants in the exemption list is deemed reasonable.

However, the use of more general terms might lead to a wide interpretation in the respective fields of application. The general terminology (e.g., screws, wedges, connectors) listed in Article 18.3 allows for an interpretation and is not always clearly defined in the medical field. Especially the term 'wedge' is not a defined medical device.

For clarification, two Team-NB Position Papers on the spinal classification[5] and the applicability of exemption rule to endosseous dental implants and dental implant abutments[6] have already been published.

The Joint NB Position Paper on spinal classification already stated, 'The term 'wedge' is not used in spine surgery and thus leaves room for wide interpretation (e.g., a cage may be seen as a wedge)'.

The MDCG 2021-11 Guidance on Implant Card – 'Device Types' lists the device types that should be indicated on the implant card and provides some clarification on the general terminology of the exempted devices in Article 18.3[7]

Due to the general terminology, there is a multitude and heterogeneity of devices that could be considered exempted from the requirements of having an implant card and to supply relevant information to the patient.

According to the General Safety and Performance Requirements (MDR, Annex I, Chapter I) a manufacturer is required to reduce any risk associated with a medical device as far as possible. For devices with a certain risk an implant card is a measure to quickly identify the implanted device and thus further reducing the potential risk of harming the patient.

The exemption of device types from the requirement of article 18 is not understood to overrule the requirement to perform a risk analysis for the device in questions in conformity with Annex I, 3. and to provide safety related information to the user in conformity with Annex I, 4. (c). The decision to provide an implant card should be based on the result of the conducted risk management by the manufacturer and may result in the decision to issue implant card also for devices within the list of exempted device types in Article 18.3.

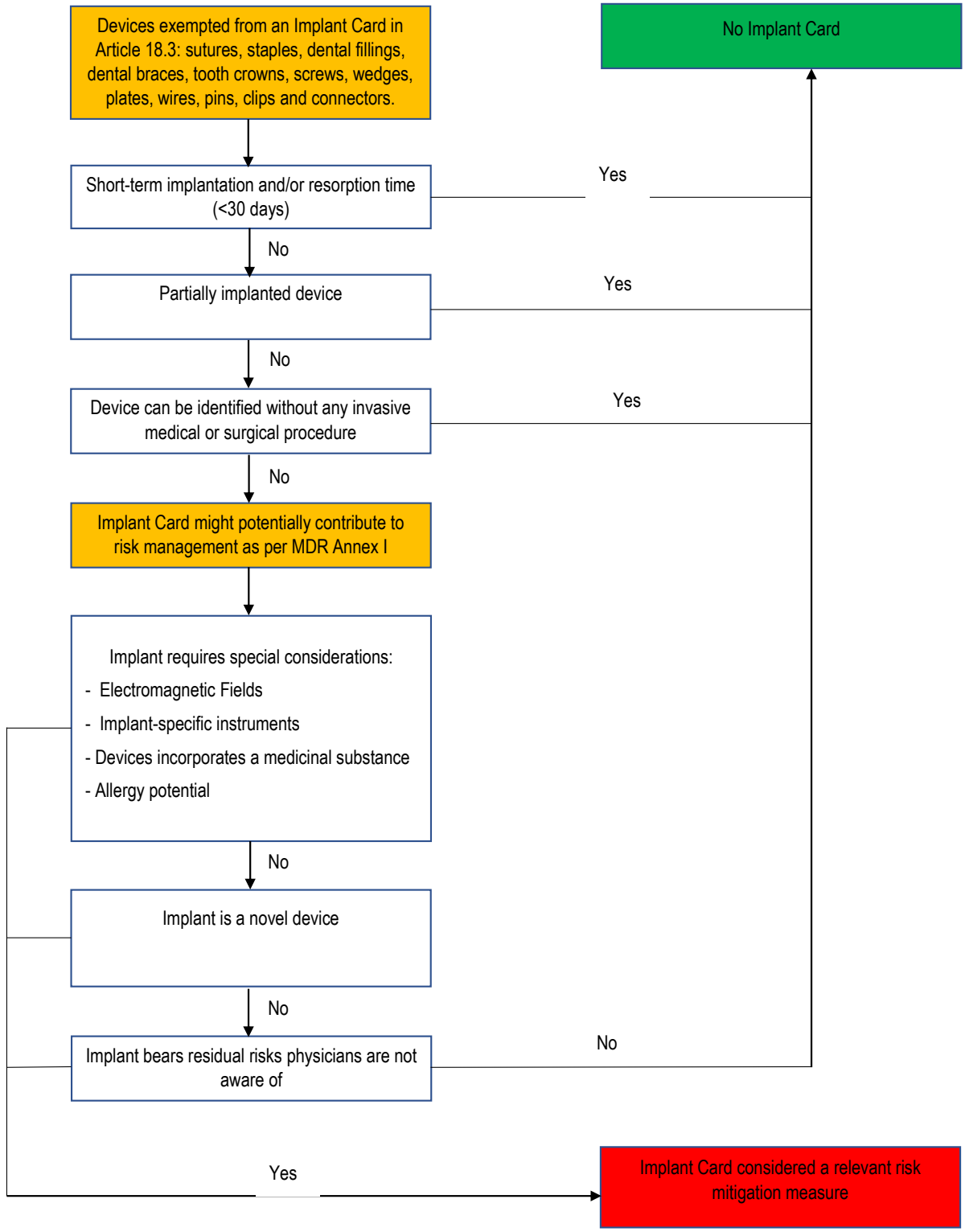
In cases when the risk management concludes that an implant card is an effective measure to mitigate the clinical risks as far as possible, the implant card should not be left out due to MDR Article 18.3. From the Notified Bodies' perspective, it is deemed necessary to highlight this fact and to provide guidance under which conditions an implant card should be considered as part of the risk mitigation. To allow for the identification of those implantable devices the flowchart in chapter 4.1 was developed.

Additionally, to the requirement in Article 18 the implant card allows the user of an implantable medical device, either the health care professional or the patient, to identify the correct Summary of Safety and Performance as required per Article 32 for the device in question.

4. Joint NB proposal on utilizing a risk-based approach on the requirement for an implant card

This chapter provides a flowchart to identify implantable medical devices for which an implant card could be considered as a relevant risk mitigation measure.

4.1 Commonly developed flowchart to determine the requirement for an implant card



4.2 Interpretation of the flowchart

The aim of this flowchart is to provide a logical and risk-based approach to identify those devices listed in Art. 18.3 for which the implant card and the supply of certain information to the patient would be considered part of the risk mitigation process as required per Annex I.

a) Devices which are short-term implants (<30 days) or have a short resorption time (<30 days)
For implanted devices with such a short lifetime in the patient there is no additional benefit of an implant card. In case of a complication in such a short time after the implantation the patient is very likely going to see the physician who implanted the device, and he/she should have all the relevant device information.

b) Partially implanted device
In case a medical device is only partially implanted and can be identified by direct vision.

c) Device can be identified without any invasive medical or surgical procedure
If no specific medical or surgical procedure with a potential harm to the patient would be required to identify an implantable device.

d) Implant requires special considerations
- Interaction to an electromagnetic field: risk mitigation for MRI, metal detectors and any electromagnetic field. Especially for an MRI it is important that the type and size of the implant is known to the radiologist to decide if an MRI scan can be done safely within the defined conditions.
- The revision and/or removal of the implant requires specific instruments
- Implant incorporates a medicinal substance
- Allergy potential: for devices incorporating a well-known allergen the implant card would allow for easier identification of the implanted materials

e) Implant is a novel device
In case of the following aspects would be considered a novel feature of a medical device:
- Novel technology
- Technology used for novel intended purpose, or a novel combination of existing technologies
- Indicated for a new disease

f) The device bears residual risks physicians are not aware of due to one of the reasons listed above or limited clinical data for the device in questions and similar devices in the State-of-the-Art.

5. Conclusion

Based on the exemptions found in the legal text of the Regulation (EU) 2017/745, this position paper documents a risk-based approach to provide guidance on how to address remaining uncertainties regarding the need for an implant card and patient information materials. The scope of this position paper is implantable medical devices listed as being exempt from the requirement of an implant card in Article 18.3 but for which an implant card should be considered as part of risk mitigation to conform with the general requirements of Annex I.

Due to a lack of clear definition and specification of the device types in Article 18.3, certain devices listed as exempted might benefit from an implant card from a risk-based perspective.

With their signature under the declaration of conformity, the manufacturer confirms, amongst others, that they have taken all efforts to mitigate the device risk as far as possible. Due to the lack of clear definition and specification of the device types in Article 18.3 for certain devices that can be exempted, based on the general terms given, an implant card and patient information materials may constitute nonetheless an effective means to mitigate the device risk as far as possible. In such cases, not providing this information by referencing to Article 18.3 without considering the results of the risk management may not be in conformity with the requirements of the MDR.

Implant cards and patient information materials may serve as a vector to promote such safety information in an effective way with a view to patient safety and clinical practice. Patients and healthcare professionals using these devices would then benefit from information for safety about the devices in the same way as they do for non-exempted implantable devices.

References

[1] *REGULATION (EU) 2017/745 of the European Parliament and the Council (5 April 2017)*

[2] *Official Journal of the European Union, Volume 60, 5 May 2017, L117/6*

[3] *MDCG 2019-8 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 (Version 2, March 2020)*

[4] *MDCG 2019-9 Guidance Document - Summary of safety and clinical performance A guide for manufacturers and notified bodies (August 2019)*

[5] *Joint NB-Position Paper on Spinal Classification per the MDR (6 December 2018)*

[6] *Position Paper Applicability of exemption rule to endosseous dental implants and dental implant abutments (Version 1;11 March 2020)*

[7] *MDCG 2021-11 Guidance on Implant Card – 'Device types' (May 2021)*