



Position Paper
Applicability of exemption rule
to endosseous dental implants and dental implant abutments

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1. Summary

Dental implants and dental implant abutments can be regarded as exempt devices according to article 18 (3) and 52 (4) based on the following points:

- The exemption list (e.g. in article 18 (3) and article 52 (4)) of the MDR contains general terminology allowing wide interpretation.
- Devices in the exemption list are required to possess a "well-established technology" [article 52 (5), MDR].
- Identification of dental implant abutments as connectors and dental implants as screws is reasonable.
- Manufacturing technologies and surgical procedures for dental implant abutments and dental implants are state-of-the-art.

2. Introduction

The medical device regulation (MDR, 2017/745) defines specific requirements for implantable devices and class III devices (e.g. article 18 (3), article 61 (4 and 6), article 52 (4), MDR) which attribute to the higher risk class of these medical devices. However, the legislator also provides a list of certain implantable devices which are exempt from certain obligations. These implants are as follows:

"sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors." [e.g. Article 18 (3), MDR]

Due to the applicability of the MDR to a broad field of medical disciplines (e.g. dentistry, orthopaedics, neurology) the use of general terminology for the description of implants in the exemption list is more than reasonable.

However, this allows a wide interpretation of these general terms in the respective field of application. For example, can dental implants and dental implant abutments be considered as implantable devices according to the exempt list (e.g. article 18 (3), MDR)?

This proposal shall address this question and provide an assessment based on the legal framework of the MDR and the professional expertise of notified bodies. A manufacturer shall always justify if his device belongs to well-established technologies (WET) enabling the notified body to conduct an independent assessment of this justification during technical documentation assessment process. Excluded from this position paper are devices which are manufactured based on new processes and/or new materials which were not used in the dental implant field previously.

3. Legal framework for dental implants and dental implant abutments

3.1 Classification of dental implants and dental implant abutments under MDR

Dental implants and dental implant abutments are currently classified as IIb medical devices [93/42/EWG, 1] which will be identical under the MDR using the applicable definition:

"an 'implantable device' means any device, including those that are partially or wholly absorbed, which is intended:

— to be totally introduced into the human body, or

— to replace an epithelial surface or the surface of the eye,

by clinical intervention and which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device." [article 2, MDR]

¹ Manual on Borderline and Classification in the Community regulatory framework for medical Devices; 2017

and classification rule 8:

"All implantable devices and long-term surgically invasive devices are classified as class IIb unless they: ..." [Annex VIII, MDR]

Based on this risk classification the specific requirements for implantable devices as laid out in the MDR apply to dental implants and dental implant abutments. These are summarized in table 1.

Table 1: Summary of articles containing specific requirements for implantable devices

Article in the MDR	Keywords of the article contents	Article contains exemption rule?
10 (8)	Requirement for document retention	No
18 (3)	Implant card and information supplied to the patient	Yes
32 (1)	Summary of safety and clinical performance	No
52 (4)	Conformity Assessment procedure	Yes
61 (4)	Clinical investigation	Yes
86 (2)	Periodic safety update report	No

3.2 Information on exemption of implants from certain requirements of the MDR

The listed requirements for implantable devices in section 3.1 attribute to the fact that these medical devices exhibit a higher risk class. However, the legislator included a list of implants that are exempt from certain requirements. This list contains:

"sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors" [article 18 (3), MDR].

Furthermore, it is stated in article 52 (5) of the MDR that *"Where justified in view of well-established technologies, similar to those used in the exempted devices listed in the second subparagraph of paragraph 4 of this Article, being used in other class IIb implantable devices, or where justified in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission is empowered to adopt delegated acts in accordance with Article 115 to amend that list by adding other types of class IIb implantable devices to that list or removing devices therefrom."*

4. Applicability of the exemption list to dental implants and dental implant abutments

4.1 Considerations regarding the legal framework

The MDR clearly defines an implantable device and states specific requirements for these medical devices. However, some requirements for implantable devices are exempt for a specific list of implants [e.g. article 18 (3) and article 52 (4), MDR].

Although, the requirements for the exempted devices are not clearly stated in the MDR it shall be attributed to the risk class and associated risks of these devices. Thus, the legislator acknowledges that a differentiation of implantable devices with identical risk classification is reasonable. The fact that dental fillings, dental braces, and tooth crowns are specifically stated in the list suggests that implantable devices for dental applications possess less severe risks compared to other medical fields (e.g. orthopaedics).

Furthermore, the legislator states in article 52 (5) that "*Where justified in view of well-established technologies, similar to those used in the exempted devices listed in the second subparagraph of paragraph 4 of this Article, ...*" indicating that in order to qualify as an "exempt device" it must be justifiably identified as a "*well-established technology*". Unfortunately, the definition of "*well-established technology*" is not given in the MDR leaving wide interpretation of this term.

Likewise, the general terminology (e.g. screws, wedges, connectors) of the listed exemption devices allows an interpretation and are not clearly defined in the medical field.

Therefore, dental implants and dental implant abutments must fulfil the following requirements to qualify as exempt devices:

- identify as an implant according to the exemption list [e.g. article 18 (3), MDR]
- possess a well-established technology

4.2 Applicability of dental implants to the exemption list

Identification as an exempted implant according to exemption list [article 18 (3), MDR]

As the term "screw" from the exemption list is not clearly identified in the medical industry it allows an interpretation. However, in the engineer field it can be defined as:

"A fastener with a screw thread cut into its cylindrical or conical shank, intended either to cut its own thread (as in a wood screw) or engage in a threaded hole." [2] It contains a screw head with a geometric feature to apply torque.

On the left side of figure 1 various types of dental implants are depicted with an external thread, a conical or cylindrical shaft and a head with a feature to apply torque. A detailed view of two example features that are used for the implant insertion are shown on the right side.

² A Dictionary of Mechanical Engineering; Anthony G. Atkins, Tony Atkins, Marcel Escudier; 2013; ISBN 9780199587438



Figure 1 Different dental implants (Dentsply, BEGO Implant Systems, Straumann) and two variations of the geometric features for the dental implant insertion.

Thus, it can be concluded that the identification of a dental implant as a screw is justifiable.

Well-established technology of dental implants

Dental implants have been introduced in the 1960 and are used ever since as a treatment option in dentistry.

Main parameters that vary in terms of dental implants are diameter, length, shape (conical or cylindrical), thread design, surface topography, and connection geometry to the surgical instrument for implant insertion (see figure 2).



Figure 2 Variations of dental implant types used in dentistry

Despite these large variations their mode of action, ensuring a fixture in the jaw bone, and intended purpose stays nearly identical. A similar assumption can be made for the surgical procedures for the implantation, thus it can be considered well-established.

Regarding the manufacturing technologies for dental implants most dental implants are made of pure titanium or titanium alloy. Thus, metal related manufacturing technologies like CNC machining are used

for their fabrication and treatments to generate a favourable surface topography are either conducted via blasting and/or etching. These technologies have been applied since decades and therefore are considered state-of-the-art.

So, it can be concluded that the requirement of a "well-established technology" for dental implants are met.

It shall be pointed out that other manufacturing technologies (e.g. ceramic processing for ceramic dental implants, 3D printing) are used for dental implants. However, since these technologies are more recently applied it shall be the obligation of the manufacturer to provide sound evidence that these technologies are well-established. In general, the application of any new novel design/materials or indications without recognised clinical experience will exclude specific dental implants from being considered as well established.

4.3 Applicability of dental implant abutments to the exemption list

Identification as an exempted implant according to exemption list [e.g. article 18 (3), MDR]

A suitable definition of the term "connector" can neither be found in the medical nor the engineering field due to its broad connotation. Therefore, it might be best described as a device that links two parts together.

A dental implant abutment is exactly intended for this purpose and connects the dental restoration (crown) with the dental implant (see figure3).

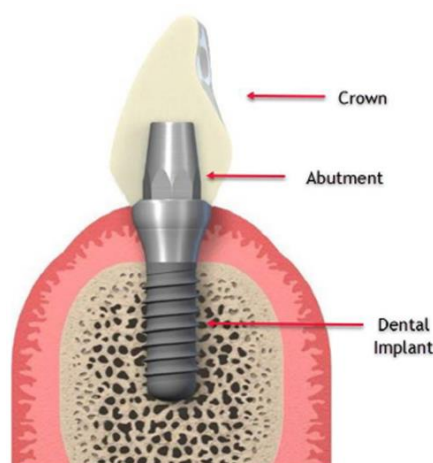


Figure 3 Dental implant abutment as connector of dental implant with dental crown

Due to the possible interpretation of the term "connector" and the intended purpose of the dental implant abutment it is reasonable to identify dental implant abutments as connectors. Since tooth crowns are clearly identified in the exception wording and the dental implant itself is justifiably defined as WET under the term screw, it follows that the abutment should also be considered as a connector for two WET devices.

Well-established technology of dental abutments

Because dental implants are used for the fixation within the jaw bone, dental implant abutments are mostly mandatory to restore the function of the natural tooth. Thus, the history of dental implant abutments is closely linked to the dental implants. Therefore, the manufacturing technologies and surgical procedures are equally well established.

5. Conclusion

Dental implants and dental implant abutments can be regarded as exempted implants according to article 18 (3) and 52 (4) based on the following points:

- The exemption list in article 18 (3) and article 52 (4) of the MDR contains general terminology leaving room for wide interpretation.
- Devices in the exemption list are required to possess a "well-established technology" [article 52 (4)].
- Identification of dental implant abutments as connectors and dental implants as screws is reasonable.
- -State-of-the-art manufacturing technologies and surgical procedures for dental implant abutments and dental implants are used.