ANDI Survey on Abutments

Replies received: 12

Countries: Germany (DE), Malta (MT), Spain (ES), Denmark (DK), Austria (AU), Lithuania (LT), Portugal (PT), Sweden (SE), Netherlands (NL), Greece (GR), Czech Republic (CZ), Latvia (LV)

Background: With regard to obligations of healthcare Professionals under Article 27 (9), MDR 2017/745 states that: "*Member States shall encourage, and may require, healthcare professionals to store and keep preferably by electronic means, the UDIs (Unique Device Identifier) of the devices with which they have been supplied*". This recommendation has already been implemented by the Italian Ministry of Health which established that healthcare professionals are required to **register and store the UDIs of class 2b implantable MDs and Class 3 implantable and non-implantable MDs (medical devices).**

1. *Such provisions encompass additional and heavy administrative burden which may be justified by the safety and health of patients when dealing with implantable devices. Do you think that similar requirements are appropriate for all other MDs and that are suitable for the sustainability of dental practices?*

DE	No
MT	I think dental implant identifiers should always be stored and from personal experience it is important even for warranty reasons. I cannot see any other dental provisions needing his requirement, whether it being a denture or a crown. **But implants, for sure yes**. Please withdraw any over regulation, in the past the system has always worked well within all divisions of dentistry and there is no need to over complicate the lives of dental personnel
ES	The maintenance of the UDI for devices other than those belonging to Class III particularly affects SMEs, resulting in unnecessary administrative burdens and additional costs that are difficult for individual dentists to bear. We therefore believe that the **UDI system should be restricted to higher-risk medical devices (Class III).**
DK	No, such requirements are not appropriate for all medical devices. The administrative burden is significant and can only be justified in very limited cases involving devices with a well-documented, high-risk profile—typically implantable devices. For commonly used equipment in dental practices, including non-implantable devices, such requirements are disproportionate and unsustainable.
AU	No

LT	We certainly do not believe that this provision is appropriate for all MDs and does not need to be expanded; it would create an additional administrative burden without adding value in terms of patient safety
PT	No. Both international and national guidelines already recommend maintaining an electronic registry of implantable medical devices, including dental implants. This measure is generally considered sufficient to meet regulatory and clinical documentation requirements.
SE	Registration requirements may be justified on the grounds of patient safety but should be limited to products that are implanted in the body or come into contact with body tissue during treatment, and should be guided by the need for traceability.
NL	No, only for the ones which stay in the body and are a high risk.
GR	No
CZ	No, it is just another increasing of costs.

2. *Do you think similar obligations might be introduced by Health Authorities of your country as well?*

DE	That would be possible.
MT	For dental implants, yes.
ES	In our country, Royal Decree 192/2023, of 21 March, regulating medical devices, which transposes MDR 2017/745, states the following in Article 36: 'In addition to the requirements of Article 27.9 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, for class III implantable devices, healthcare institutions and professionals shall store and keep, preferably by electronic means, the UDI of class IIa and IIb implantable devices supplied to them.'
DK	It is possible that health authorities in my country could introduce similar obligations, but this should be discouraged. National authorities should prioritize proportionality and avoid imposing administrative burdens that do not correspond to the actual risk involved.
AU	Possible
LT	According to the Description of the Procedure for the Use of Medical Devices, approved by Order No. V-383 of the Minister of Health of 2010-05-03, in Lithuania, Ministry of Health requires that the institution must keep and maintain up-to-date records of these implantable medical devices, except for custom-made, surgical and mesotherapeutic sutures: 39.1. all active implantable; 39.2. dental implants (excluding brackets, dental fillings, dental braces, dentures); 39.3. orthopedic implants (excluding screws, wedges, plates, wires, nails, clips, connectors); 39.4. ophthalmic implants; 39.5. cardiovascular implants; 39.6. other soft tissue implants (excluding injectable medical devices).

	40. The record book for implantable medical devices referred to in paragraph 39 shall contain the following information: 40.9. the unique medical device identifier (hereinafter referred to as 'UDI') (only for Class III medical devices). * https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.371838/asr
PT	No, although legal requirements keep evolving and our practices need to keep up with them. As mentioned in the previous answer, our national guidelines already mention keeping registry and tracking of implantable devices using electronic means.
SE	No such signals are known; this type of registry is already common due to traceability requirements, and information on which medical devices are implanted in patients is already governed by national healthcare legislation.
NL	Yes, maybe in the future.
GR	No although we do not have any cooperation with the Governmental authorities or relevant information.
CZ	No

3. *Do you think this obligation could be accepted if addressed to: a) all MDs regardless of their classification, b) only implantable MDs, c) only class 3 MDs?*

DE	This obligation could be better accepted if addressed to only class 3 MDs
MT	Only and only, dental implants. In my opinion all other provisions do not need to have a UDI
ES	We are still considering this issue.
DK	Such an obligation should only be acceptable if it is strictly limited to: b) Implantable medical devices only. A general obligation for all devices (a) or all class III devices (c) is far too broad in practice and would apply to equipment that poses no comparable risk, thereby creating unnecessary administrative workload
AU	b)
LT	As is given in the answer to question 2, in Lithuania it is obligatory only for implantable MDs and only for class 3.
PT	No. Keeping a record of every single MD used in dentistry would be a nightmare and a pile of data, with no effective advantage. Implantable MDs however, are a different case and that data should be kept and also be provided to the patient. But most of all, proper classification is mandatory and should be discussed and reviewed with the stakeholders to avoid improper classification and obligations such as the ones we are witnessing.
SE	Option C: The requirement in the MDR is essentially redundant if traceability is already ensured through medical record legislation. However, if such a registry is still to be maintained, it should focus on the highest-risk products.
NL	C, like the advise.
GR	Only Class 3 MDs
CZ	No, at all.

4. *Collagen-based hemostatic sponges are currently classified as class 3 MDs just like pacemakers, implantable defibrillators and artificial heart valves. Do you agree with this classification in light of your personal risk assessment and the higher chance of being consistent with the requirements of Article 27 (9) of MDR (as it already happened in Italy)?*

DE	No, Collagen-based hemostatic sponges should be classified in a lower risk class.
MT	Absolutely not, this is over regulation.
ES	We disagree.
DK	No, I do not agree that collagen-based hemostatic sponges should be classified at the same level as life-sustaining implants such as pacemakers. Their clinical use and risk profile are significantly different. This classification appears disproportionate and difficult to justify, particularly in the context of Article 27(9) requirements.
AU	No
LT	We would say that we disagree
PT	Absolutely not. Collagen hemostatic sponges are used routinely by dental professionals all over the world, every single day. At the very most, they could be classified as Class I as described in Chapter III, 4.4, rule 4 "intended to be used as a mechanical barrier, for compression or absorption of exsudates".
SE	Since these products are resorbed in the human body, it is reasonable that strict regulatory oversight of their manufacturing continues to apply (i.e., CE Class III). This ensures that we, as healthcare providers, can continue using these products with confidence, knowing that we are delivering safe and high-quality care.
NL	No, resorption will take place between 4-12 weeks. It will not stay forever like the examples. (collogen bovine & porcine)
GR	It is extremely demanding and without strong scientific evidence.
CZ	It is crazy.

5. *To lighten the burden associated from any measure, do you think it is advisable to propose for collagen-based hemostatic sponges a "de novo" classification as medicine, rather than MD, or its inclusion in the list of exemptions under MDR Article 18?*

DE	The effort required for the approval of a medicinal product is extremely high, so an **inclusion in the list of exemptions under MDR Article 18** is more realistic.
MT	I think it is **fair to consider it as 'medicine'**
ES	We believe that it would be more consistent to include it in the **list of exemptions** in Article 18 of the MDR.
DK	Yes, it should be strongly considered **either to reclassify these products as farmaceutical products or to include them under the exemptions listed in Article 18.** This would reduce the burden for clinicians and ensure a more proportionate regulatory approach.

AU	Yes
LT	It would be more appropriate to add it to the **list of exemptions.**
PT	Yes, of course. There's no sense in keeping collagen-based hemostatic sponges in the same category as a dental implant, for example. As already stated in the **above mentioned Article 18, regarding exclusions**: for instance, sutures (regardless of being resorbable and requiring no removal by the doctor from the patient), are already part of that list of exclusions as should the collagen sponges be.
SE	In that case, **an exemption** pursuant to Article 18 would apply.
NL	Inclusion **in the list of exemptions** under article 18.
GR	It is better to be included in the list of exemptions under MDR Article 18.
CZ	Into list of exemptions.

6. *Dental implant abutments are classified as class 2b MD. Do you believe that risk associated with this MD is comparable to that exhibited by other class 2b MD, such as ventilators or intensive care monitor equipment and therefore it might be considered as inconsistent?*

DE	Due to the associated risk dental implant abutments should be classified as class **2a medical device**.
MT	It is important to have quality control over the manufacture of implant abutments as poor quality manufacturing can lead to disastrous results which could affect the patient both physically and financially. So I fully understand that these components must be manufactured to a very high standard, for design, strength, biocompatibility and precision. This is of highest importance**, so if the specifications of manufacture have to be high, then they should fall in the category of the machinery mentioned above. However it has to be also mentioned that they are not critical to life as a ventilator.**
ES	We consider that **the risk is lower** and that it could be considered inconsistent.
DK	**No, the risk associated with dental implant abutments is not comparable to that of devices such as ventilators** or intensive care monitoring equipment. The current classification appears inconsistent and should be reassessed to ensure a more balanced evaluation.
AU	No
LT	No
PT	These are evidently distinct categories of medical devices (MDs) and, as such, should not be grouped under the same classification. This highlights the urgent need for **a specific and appropriate classification system for MDs used in dentistry, developed with input from all relevant stakeholders**. While the general classification of MDs is acknowledged as necessary, the particularities of dental practice suggest that a tailored classification for dental MDs may be more relevant, facilitating both understanding and compliance by dental professionals.
SE	Classification as Class IIB is reasonable. It is based on Rule 8 of Annex VIII of the MDR and ensures that we can have confidence in the products we use. Lower control requirements (Class IIa) imply reduced safety. The issue is not the safety standards applied during manufacturing, but rather the bureaucracy created by the MDR. Let us focus on the real problem.
NL	**The risk is not comperable**, an abutment should be on the list in article 18.

GR	**It is wiser to be Classified as Class 2a.**
CZ	It is **incosistent,**

7. *The EU Association of Notified Bodies in a position paper on the "Applicability of exemption rule for dental implants and abutments" suggested that these MDs might be included in the exemption list under Art 18 (3) of MDR. Alternatively, Abutments could be classified as class 2a MD, according to the rule 5 of Annex VIII of MDR. Do you think these are reasonable alternatives to the current classification?*

DE	Yes, these are reasonable alternatives.
MT	This question here is not clear at all, is it referring to implants and abutments, or abutments alone? I do not think they should be tackled together. An implant has to be numbered and this info has to be stored. An abutment not so. However both have to be made to the highest standards and be biocompatible. 2a classification is for a MD to be used temporarily for up to 30 days, so I do not see how this classification is possible with either implants or abutments. The abutment has to be treated with care and attention when dealing with classification, more than that of a crown or a denture as its failure is much more detrimental to health at times that that of a crown. In addition, an abutment can also be submerged into the gingivae unlike most dental restorations, so again more care has to be given to the manufacturing of these devices. **To conclude, the quality of both implants and abutments has to be given utmost importance and need to be manufactured extremely well to withstand years of use. The only difference between the two is that an implant should have a UDI and these details should be stored by the dental team/clinic.**
ES	Yes, we consider them to be reasonable alternatives.
DK	Yes, these are sensible and necessary alternatives. Reclassification to class IIa or exemption under Article 18(3) would be far more proportionate to the actual clinical risk and would reduce unnecessary bureaucracy for dental professionals.
AU	Yes
LT	It would be more **appropriate to add it to the list of exemptions**.
PT	Classifying abutments **as a class 2a MD, in our opinion makes no sense considering the rule 5 of Annex VIII, which clearly states that unless they are used for "short term", since they are being used in the oral cavity they should be considered as a class I MD**. Since an abutment is connected to a dental implant, and we expect the lifespan of that implant to be long, they should not be considered of "short term" usage.
SE	An exemption under Article 18 seems reasonable. Reduced requirements for manufacturing control – no. Lowering the classification, and thereby reducing requirements for the manufacturer, benefits neither dentists nor patients.
NL	Yes, see comment above.
GR	ABSOLUTELY

CZ	Yes, but even all MDR is just complication for patients and Dentists.

Latvia's response on the survey:

Currently, according to Cabinet of Latvia Ministers Regulation No. 461 of 15.08.2023 'Medical Devices Regulations' 47.5, the unique identifiers of active class IIa, active class IIb, and class III medical devices supplied to them must be stored electronically for at least two years. For dental healthcare institutions, information should only be stored about dental equipment, X-ray machines, autoclaves, and other energy-operated devices. During inspections at distributors and importers, we explained about UDI and how the traceability of medical devices is ensured. In healthcare institutions, the information must be recorded in the institution's developed Medical Device Operation System.