March 2026

Position on the

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I

The TÜV Association welcomes the European Commission's initiative to revise Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). The implementation of both regulations led to a multitude of issues and open questions in the past. Nevertheless, both regulations achieved their intended purpose of providing a very high level of safety, which risk being compromised with the current Commission proposal.

While we welcome that there will finally be exemptions for orphan devices und breakthrough devices and a more extensive and mandatory exchange of experience between notified bodies, a number of provisions are highly critical in our view for two different reasons.

First of all, the proposed reduction of the notified body involvement in conformity assessment procedures – from initial certification assessments to continuous surveillance activities – represents a serious weakening of the EU's medical device safety framework.

Second of all, some proposals would make it difficult or impossible for notified bodies to operate economically and jeopardize their continued existence, while others would place a significantly greater burden on medium-sized and large manufacturers and lead to considerable distortions of competition between manufacturers.

Table of contents

General remarks

Updating the EU medical devices framework without compromising patient safety

The proposed reduction of the notified body involvement relates in particular to the proposals below which, taken together, undermine the high level of protection (for a comprehensive overview, see Annex I "MDR: Overview on involvement into the conformity assessment procedures from the initial certification assessments to continuous surveillance activities" and Annex II "IVDR: Overview on involvement into the conformity assessment procedures from the initial certification assessments to continuous surveillance activities"):

- downgrading a number of high-risk products / introducing vague and generous well-established technologies (WET) categorisations affecting high-risk products in particular,
- reducing systematic audit activities,
- removing unannounced audit requirements of products,
- reducing the mandatory systematic technical documentation assessment of representative product groups and shifting the mechanism from a minimum number or minimum percentage of products to "for cause" assessments.
- eliminating the standalone product/group specific periodic safety update report (PSUR) reviews,
- deleting the maximum validity period of certificates, thus abolishing re-certification requirements completely.

Taken together, these measures substantially erode the ability and probability to detect safety and performance-related issues of products before they are placed on the market, thereby dismantling the precautionary principle to prevent harm before it occurs. These changes together risk shifting the role of notified bodies from a proactive oversight role to a predominantly reactive role, in which issues are identified only after serious hazards or widespread complaints have occurred. As a result, the current proposals would reduce the level of protection to that of previous legislation[1], delay the identification of emerging or systemic risks, and increase the likelihood that unsafe or non-compliant devices remain in clinical use. The inevitable consequence is an increased risk to patients and healthcare in general.

To give an example, the proposal that certain reports shall no longer be sent regularly to notified bodies, but be reviewed as part of surveillance and technical documentation assessment procedures instead, may be a sensible measure in principle. However, if at the same time after initial certification there is no systematic technical documentation assessment sampling foreseen anymore and the frequency of surveillance audits halved, the negative effects are exacerbated: The scope and quality of medical devices assessments and monitoring suffer, with a significant impact on product and patient safety.

Market economy and competitive principles are ignored

With the proposed Regulation, the European Commission obliges notified bodies to grant micro-enterprises a discount of at least 50% and small enterprises a discount of at least 25% on their fees for

[1] Medical Device Directive (93/42/EWG), Active Implantable Medical Devices Directive (90/385/EWG), In Vitro Diagnostic Medical Devices Directive (98/79/EG)

their services. In addition, notified bodies shall grant a 50% discount on their fees for the conformity assessment of orphan devices. Around 80% of notified bodies' customers are SMEs.

Reduced fees for micro and small enterprises and manufacturers of orphan devices can be applied to public services as these authorities are publicly financed through taxes. This allows for lost revenues and deficits to be offset. However, this is not the case for private companies. Transferring this responsibility to notified bodies would lead to significant distortions when it comes to placing medical devices on the market. Notified bodies are almost exclusively private companies and thus bound to the rules and constraints of the free market economy. In contrast to public activities, notified bodies also bear all liability risks associated with their activities by themselves. If notified bodies are forced to offer high discounts, their services would operate at a loss. This could have significant negative consequences for notified bodies, manufacturers and patients.

Economic interests must not compromise patient safety

The aim of any revision must be to abolish unnecessary or adapt unsuitable requirements, while retaining the relevant ones. As for the Commission proposal, however, the objective to improve the economic conditions for manufacturers will most likely lead to an increase of the risks for patients and users in the medium to long term. It is clear though that patient safety must under no circumstances be compromised by the planned measures. Economic interests may only be taken into account when they do not jeopardize product safety and thus patient safety.

Furthermore, the proposed measures will have no significant economic impact. The costs of conformity assessment by the notified bodies account for less than 10% of compliance costs of manufacturers.

Acceptable and non-acceptable simplifications

This being said, some of the proposed reductions in monitoring frequency and monitoring intervals make sense in order to relieve the burden on manufacturers and notified bodies. Nevertheless, this applies only insofar as other measures are not implemented that significantly reduce the overall level of product and patient safety. The proposed reductions which are in our view acceptable include:

- removal of the maximum validity period of certificates issued by notified bodies (Art. 56 and Annex VII 4.8 and 4.11), replaced by periodic reviews;
- reduction of the frequency for updating the periodic safety update report (PSUR) depending on the risk class of the device (Article 86 MDR and 81 IVDR);
- reduction in the number of products for which a summary of safety and clinical performance (MDR) and the summary of safety and performance (IVDR) must be established;
- the removal of the requirements for a notified body certificate for relabelling and repackaging activities, as well as the prior notice obligation.

Other reductions in pre- and post-market assessments and further surveillance intervals can compromise product and patient safety, especially if the aforementioned measures are equally implemented:

- for the initial certification: reduction of the number of samples of technical documentation to be reviewed by notified bodies as part of the assessment of quality management systems;

- for the continuation of the QMS certification abolishment of any systematic technical documentation assessment
- abolition of regular unannounced audits;
- requirement that, under certain conditions, surveillance audits and assessments should only be carried out every 24 months instead of every 12 months;
- reduction of monitoring requirements for class III devices that are a well-established technology.

Please find below our detailed recommendations that aim to ameliorate the Commission proposal.

Summary of recommendations

1. Notified body operations: Do not jeopardise core market economy principles

- Delete subparagraphs 2, 3, 5, and 6 in Article 1(40).
- Do not introduce mandatory fee reduction provisions for micro and small companies and instead consider providing financial incentives such as public subsidies for certification procedures.

2. Sample size: Do not reduce the sample size of technical documentations

- Delete Article 1(43) (a), Annex I(5)(q)(ii) and (7)(a) and (e), Annex II(5)(s)(i)(2) and (6)(a) and (e).
- Define concrete requirements for sampling prior to issuing a QMS certificate and during surveillance after issuing the certificate.

3. Unannounced audits: Do not reduce the scope and frequency of unannounced audits

- Maintain the original monitoring and assessment provisions by deleting Annex I(7)(d) and Annex II(6)(d).

4. Surveillance audits: Do not reduce the frequency of surveillance audits and assessments

- Delete the requirement in Article 1(7)(c) and Article 2(6)(c) that provide for surveillance audits and assessments to be carried out every 24 months instead of every 12 months under certain conditions.

5. Class III devices and well-established technologies: Do not introduce unclear definitions

- Delete the definition of WET (Article 1(2)(e)).
- Establish a list of products falling under the WET definition by the EU Commission or make a binding decision by an expert panel.
- Do not reduce monitoring requirements for class III devices classified as WET, only allow facilitation measures provided for in Article 61(6), Article 1(43) (a)should be deleted and Annex I (7)(e) should be adjusted.

6. Classification requirements: Do not downgrade classification requirements

- Delete the possibility to not involve a notified body for class Ir medical devices in Article 1(43)(e)(ii).
- Do not downgrade classification from class III to class Ir, delete Annex I(6)(c) and (d).
- Do not change the definition of medical device, delete Article 1(2) (a).
- Secure and maintain the requirements for sterile conditions, delete Article 2(29)(h).

7. Dispute settlement: Do not establish unsuitable procedures

- Delete the procedure for dispute settlement (Article 1(27)(a)).

8. Timelines: Introduce clear timelines for every step of the notification procedure

- Add clear deadlines in Articles 1(30) and (35)(e) to be met by notifying authorities.

9. Regulatory sandboxes: Separate regulatory sandboxes from conformity assessment procedures

- Clarify Articles 1(59) and 2(36) that a regulatory sandbox participation does not lead to a presumption of conformity.

Recommendations in detail

1. Notified body operations: Do not jeopardise core market economy principles

Reduction of fees

With the proposed Regulation, the European Commission obliges notified bodies to grant micro-enterprises a discount of at least 50% and small enterprises a discount of at least 25% on their fees for their services (Article 50(2) & (3) MDR). In addition, notified bodies shall grant a 50% discount on their fees for the conformity assessment of orphan devices (Article 50(2) MDR).

In Recital 27, the Commission states as justification that
"Even though most notified bodies are private for-profit entities, they exercise their function in the public interest. With regard to manufacturers that are micro or small enterprises within the meaning of Commission Recommendation 2003/361/EC16 and with regard to orphan devices, notified bodies should therefore be required to reduce their fees for conformity assessment activities in accordance with Regulations (EU) 2017/745 and (EU) 2017/746."

The overall intention to promote micro and small enterprises and manufacturers of orphan devices is to be welcomed and important for innovation, supply chain security and quality. However, the measure chosen is completely inappropriate.

Reduced fees for micro and small enterprises and manufacturers of orphan devices can be applied to public services as these authorities are publicly financed through taxes. This allows for lost revenues and deficits to be offset. However, this is not the case for private companies. Transferring this responsibility to notified bodies would lead to significant distortions when it comes to placing medical devices on the market. Notified bodies are almost exclusively private companies and thus bound to the rules and constraints of the free market economy. In contrast to public activities, notified bodies also bear all liability risks associated with their activities by themselves.

If notified bodies are forced to offer high discounts, their services would operate at a loss as around 80% of notified bodies' customers are SMEs.[2] This could have significant negative consequences:

a. Services that were economical before would become uneconomical and thus no longer be offered. Notified bodies could limit their range of services or cease business activities entirely. Many micro and small enterprises would no longer be able to find a notified body, as they make up a large proportion of all manufacturers, but certification would no longer be economically viable.

b. To continue offering economical services, notified bodies would have to increase the fees for all other manufacturers to remain profitable altogether. Larger manufacturers would thus indirectly subsidise smaller manufacturers.

c. Manufacturers who do not benefit from the reduced fees would have an incentive to modify their organisational structure so that they do benefit. Ultimately, in the most extreme case, all

[2] Team-NB Medical Device Survey 2024, page 23

manufacturers would fall under the definition of micro and small enterprises – which would not change the status quo as notified bodies would adjust their prices accordingly.

The obligation for private companies to offer discounts on their services without receiving financial compensation constitutes an unprecedented move in EU legislation and a massive intervention in the European economic system. If the Commission's argumentation of notified bodies as a public service provider is strictly followed, such a principle would equally have to be applied to all private companies providing public services in the areas of for instance energy and water supply, transport, education, healthcare, etc.

It also must be borne in mind that such a move would not only benefit European manufacturers, but also manufacturers from third countries. In fact, more than half of all medical devices manufacturers (53%) come from third countries [3] – most of them from China, the U.S. and Switzerland. It is questionable whether the European Union wants to primarily subsidize non-EU manufacturers in the current geopolitical context. In macroeconomic terms, this would be a loss for Europe.

Deferment of payments

In addition, the European Commission wants to oblige notified bodies to grant micro and small manufacturers the possibility to defer payments until the relevant conformity assessment is finalised. This measure would put significant economic pressure on notified bodies as maintaining solvency would become more difficult. Notified bodies would have to provide considerable advance services to manufacturers and would lose interest income. This would result in higher costs for notified bodies and, in turn, in potentially more restrictive payment requirements and higher fees for all other manufacturers.

Moreover, such requirements also put significant economic pressure on notified bodies to complete their assessment procedures as quickly as possible. This stands in contrast to a core provision of both the MDR (Article 53(5)) and the IVDR (Article 49(5)), according to which:

"*Notified Bodies and the personnel of Notified Bodies shall carry out their conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific field and shall be* ***free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities,*** *especially as regards persons or groups with an interest in the results of those activities.*"

Processing times

Moreover, the Commission also wants to oblige notified bodies to "deal with any request for conformity assessment activities from a manufacturer (…) within 15 days of receipt of the request" (cf. Article 50(5)). This requirement, however, is completely unrealistic. It would require notified bodies to hire significantly more staff to be able to meet these deadlines for all assessments at any time. This would make conformity assessment procedures become significantly more expensive without any significant added

[3] Team-NB Medical Device Survey 2024, page 22

value.

Contracting obligation

Finally, the European Commission would also like to give competent authorities the power to instruct a notified body to accept a manufacturer's request for conformity assessment when duly justified in the interest of public health, patient health or safety (cf. Article 50(6)). Looking at the realities of notified bodies operation's, this requirement does not make sense though: A rejection of a manufacturer is usually due to the fact that either no further capacities are available or that there is sufficient evidence that the manufacturer does not meet the requirements of the MDR or IVDR. In the latter case, even an imposed procedure by the authorities would not lead to a successful certification. There are already provisions in the current regulations (Articles 59 MDR / 54 IVDR), which do not need to be further tightened.

Our proposals

- Maintain subparagraphs 2, 3, 5, and 6 in Article 1(40).
- Do not introduce mandatory fee reduction provisions for micro and small companies, but instead consider providing financial incentives such as public subsidies for certification procedures.

→ Proposal for amendments

2. Sample size: Do not reduce the sample size of technical documentations

The Commission's proposal aims to significantly reduce the number of samples of technical documentations to be reviewed by notified bodies as part of the assessment of quality management systems.

„For lower and medium-risk devices, the involvement of notified bodies in the conformity assessment process should be reduced so that it is proportionate to the risk class of the device. For example, for class IIa and non-implantable class IIb devices, or most class C devices, where the notified body is to assess the technical documentation on a sampling basis, it should be clarified that the technical documentation assessment is only needed for one representative device of a category of devices or a generic device group, or in the case of class B devices only for one device from the manufacturer's product portfolio. Additional technical documentation assessment during surveillance activities should only be carried out when potential concerns exist based on data available from the post-market surveillance system. As class A sterile devices are of low risk, notified body involvement for those devices should be removed." (Recital 30)

The proposed reduction of many monitoring and assessment mechanisms means that the frequency of sample reviews will fall back to the level prior to the MDR and IVDR. Particularly for manufacturers with a large product portfolio or many products under one quality management system, this could mean that the technical documentation for individual products is never reviewed by a notified body throughout their entire life cycle. As a result, notified bodies will not be able to act proactively, but can only react reactively after incidents have occurred. In other words, notified bodies will have to limit their work on the control and evaluation of theoretical processes, instead of assessing the practical implementation of medical,

technical, and scientific requirements. This makes it significantly more difficult to prevent and avoid incidents. For society as a whole, the costs could rise significantly as a result of reduced prevention and necessary corrective measures.

In our view, this massive reduction of monitoring measures would lead to the consequence that a consistent high level of patient safety cannot be achieved. Incidents that led to the establishment of the MDR and IVDR (as a result of issues with manufacturers and products) could most likely not be prevented. It is not in the interests of patient safety to lower this monitoring mechanism to such an extent that the requirements fall back to the level of the MDD and IVDD.

Moreover, such a reduced sample size is also far too small in international comparison that take into account scientific principles and conditions (e.g. FDA's "Guide To Inspections of Quality Systems"[4], ISO 2859-1:1999 standard "Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection"[5]). Adjustments and exemptions in sampling must aim to maintain an equivalent level of safety while providing the greatest possible relief to manufacturers, especially SMEs.

Sampling - alternative proposal

Following the provisions set out in MDCG 2019-13 rev. 1[6], the sampling should be based on quantitative and qualitative criteria both prior to initial certification and during surveillance activities. These criteria need to focus on being representative of the intended use and subsequently the safety aspects related to them. The MDCG-approach for classes IIb and IIa (which in some cases is only a prolonged application time or "higher" invasiveness), shall be replaced by an approach focusing on the intended use and the related safety aspects. Therefore, the separation into generic device groups (class IIb using EMDN[7] codes level 4) and categories of devices (class IIa using MDA/MDN codes[8]) should be replaced by applying level 3 EMDN codes for class IIb and IIa. The notified body shall assess at least one sample of the level 3 EMDN code, applying a risk approach that prioritizes class IIb products over class IIa in the same EMDN code for the assessment prior to issuing an EU certificate referencing this group of devices.

The purely figure-oriented approach of sampling a percentage of devices covered under the scope of the certificate (see MDCG 2019-13 rev. 1) does not sufficiently address the risks related to the device and endangers the patient. It only fulfils a non-statistically supported sampling size, leading to unnecessary repetition of assessments that would especially lead to an additional burden for small and medium manufacturers.

For the sampling during surveillance, together with every surveillance audit, at least one representative

[4] Food and Drug Administration – Guide To Inspection of Quality Systems (August 1999)
[5] ISO 2859-1:1999, Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
[6] MDCG 2019-13 Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation
[7] European Medical Device Nomenclature (EMDN)
[8] MDCG 2019-14 Explanatory note on MDR codes (MDA/MDN code)

sample of the EMDN level 3 code – subdivided by active and non-active devices - shall be subject to the technical documentation assessment, as long as the previous assessments did not cover the same product (Basic UDI-DI). Further, we would remove requirements sampling an entire Basic UDI-DI to one device only.

The TÜV Association strongly recommends retaining the risk-based systematic assessment of technical documentations over the validity of a certificate. The sampling shall be adapted to allow, for example, efficiencies by risk-prioritised modular technical documentation assessments. A modular technical documentation assessment means that only relevant and specific requirements of Annex I MDR/IVDR are assessed. The relevance for specific product types shall be defined in product specific common specifications or guidance, supporting a harmonized and uniform implementation (e.g. general safety & performance, risk management & QMS integration, biological safety & materials, infection control & sterility, physical, mechanical & electrical safety, software & usability & cybersecurity, clinical performance & evidence, labelling & user information). In order to avoid unnecessary duplication of assessments, the depth of the surveillance assessments shall at least cover the post-market surveillance aspects as well as Chapters I and II of Annex I MDR/IVDR.

This refined proposal aims to balance regulatory rigor with practical considerations, ensuring that assessments are both effective and efficient, particularly for smaller manufacturers. By focusing on intended use and safety aspects, the approach aligns with the overarching goals of Regulations (EU) 2017/745 and (EU) 2017/746 and MDCG 2019-13 rev. 1.

Our proposals

- Delete Article 1(43)(a), Annex I (5)(q)(ii) and (7)(a) and (e), Annex II (5)(s)(i)(2) and (6)(a) and (e)
- Define concrete requirements for sampling prior to issuing a QMS certificate and during surveillance after issuing the certificate

→ Proposal for amendments

3. Unannounced audits: Do not reduce the scope and frequency of unannounced audits

Unannounced audits were deliberately introduced in 2013 with the Recommendation 2013/473/EU and later incorporated into the MDR and IVDR as a key measure to detect fraud and ensure that manufacturers continuously comply with their quality management systems. The MDR states its rationale as follows (Recital 12):

"The position of notified bodies vis-à-vis manufacturers should be strengthened, including with regard to their right and duty to carry out unannounced on-site audits and to conduct physical or laboratory tests on devices to ensure continuous compliance by manufacturers after receipt of the original certification".

The European Commission's new MDR and IVDR proposals already aim to reduce a large number of monitoring and assessment mechanisms. This reduction makes the availability of unpredictable

monitoring mechanisms even more important. Otherwise, notified bodies and authorities will only be able to respond to developments and incidents "for cause" – preventing notifying bodies from detecting non-compliances before incidents occur. This reduced prevention is likely to lead to higher costs for society as ex-post corrective measures are needed in return

Generally speaking, the European legislator must ensure that even a revised MDR and IVDR contains sufficient provisions that ensure that the incidents that led to the adoption of the MDR and IVDR are prevented. In other words, a consistently high level of patient safety must be ensured. With the proposed massive restriction of unannounced audits by notified bodies, this would clearly not be the case. It is not in the interest of patient safety to reduce these monitoring provisions to such an extent that they fall back to the level that existed before.

Our proposals

- Maintain the original monitoring and assessment provisions by deleting Annex I (7)(d) and Annex II (6)(d).

→ Proposal for amendments

4. Surveillance audits: Do not reduce the frequency of surveillance audits and assessments

The proposed requirement in Article 1(7)(c) (and Annex IX (3.3) of the MDR / IVDR) that, under certain conditions, surveillance audits and assessments should only be carried out every 24 months instead of every 12 months, creates legal uncertainty and leads to highly diverging interpretations. The current MDR and IVDR have been suffering from unclear or overly generic requirements, which in turn required the publication of a substantial amount of MDCG documents to clarify the interpretation. The European legislator should not make the same mistake again.

This is due to the fact that the proposal does not lay down specific requirements for the reduced frequency of surveillance audits, and contains several undefined legal terms. Examples here are the wording "justified in light of the results of previous surveillance audits and assessments" and "in the absence of any concerns resulting from data from post-market surveillance or vigilance". This sets the basis for an unequal treatment of manufacturers, resulting in discussions and potential legal disputes between manufacturers and notified bodies. And, after all, an inconsistent implementation across Europe.

Furthermore, the proposed provisions contradict other certification requirements (in particular MDSAP[9] certification and EN ISO 13485[10] certification), stipulating regular certification (in a three-year-

[9] Medical Device Single Audit Program (MDSAP) allows a recognized Auditing Organization (AO) to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of participating Regulatory Authorities.
[10] ISO 13485 is the international standard for quality management systems in the medical device industry. It specifies requirements for the entire product life cycle (from development and manufacturing to disposal) in order to ensure safety and effectiveness. It is essential - but not mandatory - for compliance with legal regulations such as the MDR.

certification-period) and annual monitoring requirements and usually combined with the monitoring provisions under MDR and IVDR.

In order to ensure uniform requirements and competitive conditions, surveillance audits and assessments should continue to take place every 12 months.

Our proposals

- Delete the requirement in Article 1(7)(c) and Article 2(6)(c) that provide for surveillance audits and assessments to be carried out every 24 months instead of every 12 months under certain conditions.

→ Proposal for amendments

5. Class III devices and well-established technologies: Do not introduce unclear definitions

We welcome the fact that the European Commission proposes simplifications for the conformity assessment of well-established technologies (WETs). However:

- The newly introduced definition of WET is ambiguous: It is left to the interpretation of manufacturers and notified bodies to determine what "simple, common and stable", "safety issues", "in the past", "little evolution" and "long history" exactly mean. The definition is likely to lead to inconsistent interpretations by manufacturers, notified bodies and authorities – contradicting the European Commission's original objective of defining clear requirements and preventing differing interpretations.
- The definition of WET only refers to the "generic device group". It does not relate to a specific product, but rather a large number of products that a manufacturer may not even produce itself, but for which it must provide the relevant evidence. Many manufacturers will not be able to meet this requirement, and the lack of clear guidelines will lead to inconsistent implementation by the notified bodies.
- The proposition to allow class III devices to benefit from reduced monitoring requirements bears significant risks to patient safety. From our experience, a number of products that caused problems in the past would fall under the WET classification requirements. Therefore, simplification should be limited to class IIa and IIb devices, but not encompass class III devices.

Our proposals

- Delete the definition of WET (delete Article 1(2)(e)).
- Establish a list of products falling under the WET definition by the EU Commission or make a binding decision by an expert panel.
- Do not reduce monitoring requirements for class III devices classified as WET, only allow facilitation measures provided for in Article 61(6), Article 1 (43) (a) should be deleted and Annex I (7) (e) should be adjusted.

→ Proposal for amendments

6. Classification requirements: Do not downgrade classification requirements

Requirements for class Ir

The Commission proposes that manufacturer may not involve a notified body, if the manufacturer self-declares that relevant harmonized standards or Common Specifications have been applied. If he doesn't self-declare this, he has to involve a notified body. This suggested approach is not comprehensible as also the notified body has to take into account the relevant harmonized standards, and Common Specification or state-of-the-art criteria.

Specifically in combination with the proposed down-classification in Annex VIII, rule 6 and 7 "regardless of the body part with which they come into contact" the proposed removal of scrutiny for those devices is concerning for patient's safety.

- 80% of lifetime data including biocompatibility are lacking full evidence.
- 50-80% of manufacturers outside of the central European region abandon a disinfection step before sterilization in IFU and efficacy testing thereof.
- According to well-established accredited test laboratories, recognized for ISO 17664, 95% of MDR triggered reprocessing validations are insufficient and not comply with the claimed harmonized standard EN ISO 17664. More specific, the client is not able to present an IFU with correct reprocessing instructions complying with ISO 17664 and related standards and guidelines.
- Additionally, during the assessment of the reprocessing procedures often incorrectly classified devices are identified (class III/IIa instruments declared as Ir). This would not be detected anymore.

In addition, the Commission proposes to change the classification rule 6 and 7 in Annex VIII MDR. Reusable surgical instruments shall be classified in class I, regardless of the body part with which they come into contact.

By these proposed changes, some products will be reclassified from class III to class Ir. The Commission do not appropriately take into account the intended purpose and inherent risk of these devices and are therefore not congruent with the clear intent of MDR definitions.

Concerns related to device safety and performance

The current classification of surgically invasive instruments for use on the central nervous system (CNS) and central circulatory system (CCS) in class III is based on the high vulnerability of the regions mentioned and the associated correspondingly high risk potential and potential damage, but not on the technical complexity of the devices (e.g. instruments). Interventions on the structures of the CNS and CCS carry the highest risk on the part of the patient. For example, in the CNS even the slightest errors, contamination or material defects can lead to permanent neurological deficits, paralysis, cognitive damage and death.

If products with highest risk, in this case based on the vulnerability of the human body, will be classified in

the lowest device risk category, systematic monitoring of production and design is not guaranteed. This is to be regarded as critical, as most instrument-related notifications from the market originate in production and quality system issues. The relatively low number of reportable/reported vigilance cases for Class III instruments is very likely due to the currently very well-functioning monitoring of product design and manufacturing by notified bodies.

A significant down-classification of reusable surgically invasive instruments with direct contact to the CNS and CCS from class III to class Ir in combination of the removal of the notified body involvement will therefore have a negative impact on the safety of the products and thus the patient.

Definition of a medical device

The Commission proposes in Article 1 (2) (a) to change the definition of medical device:

"The following products shall also be deemed to be medical devices:
- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) ~~and of those referred to in the first paragraph of this point~~."

It is not clear, why devices for cleaning, disinfection or sterilisation of e.g. non-active medical devices are excluded now. In the interests of product safety and thus patient safety, this proposed amendment should not be adopted.

Securing and maintaining sterile conditions – involvement of notified bodies

The Commission proposes to delete the second subparagraph in Article 48(10) IVDR:

"However, if those devices are placed on the market in sterile condition, the manufacturer shall apply the procedures set out in Annex IX or in Annex XI. Involvement of the notified body shall be limited to the aspects relating to establishing, securing and maintaining sterile conditions."

This could be a big safety issue for patients. For Class A sterile IVDs, e.g. for blood collection tubes with an open connection to a venous or arterial puncture needle (class IIa MDR) studies confirmed that blood collection tubes must be sterile due to the risk of backflow of blood into the patient's venous system. This can happen due to changes in the pressure if the tourniquet is released while the tube is still connected and the vacuum is exhausted, the sudden drop in venous pressure can pull fluid back from the tube. It can also happen by holding the tube above the puncture site which allows gravity to facilitate the movement of contents back into the vein.

Significant lack of experience among IVD manufacturer with sterile products in general, and particularly with a sterile validation, already now resulting in a relatively high number of safety issues.

Our proposals

- Delete the possibility to not involve a notified body for class Ir medical devices in Article 1 (43) (e) (ii).
- Do not downgrade classification from class III to class Ir, delete Annex I (6) (c) and (d).

- Do not change the definition of medical device, delete Article 1 (2) (a).
- Secure and maintain the requirements for sterile conditions, delete Article 2 (29) (h).

→ Proposal for amendments

7. Dispute settlement: Do not establish unsuitable procedures

The Commission proposes a new procedure of dispute settlement between manufacturers and notified bodies. The proposal stipulates that "a manufacturer or notified body may raise with the authority responsible for notified bodies, in a duly substantiated manner, any unresolved dispute arising from the application of the requirements set out in Annex VII and the involvement of a notified body in the conformity assessment in accordance with Article 52 and Annexes IX, X and XI."

The introduction of such a procedure would clearly weaken the role of the notified bodies – as it would be possible to question every decision made by a notified body at every stage of the procedure. In case of doubt, such a procedure only delays ongoing certification procedures. It also does not add any value, as it is not binding on either manufacturers or notified bodies. Furthermore, it completely disregards liability issues arising from the relevant decisions by the authorities.

Our proposal

- Delete Article 1(27)(a).

→ Proposal for amendments

8. Timelines: Introduce clear timelines for every step of the notification procedure

The adjustments proposed by the Commission for Articles 38 to 42 MDR within the framework of the notification procedures are to be welcomed. Although the MDR and IVDR have led to a certain degree of harmonisation of the designation procedures, there is still a long way to go before uniform procedures and requirements are achieved in practice. In order to create a level playing field and speed up procedures, the measures must go even further: Clear timelines for every step of the notification procedures are needed. This is due to the fact that the notification and monitoring procedures continue to take a very long time, especially when joint assessment teams are involved. In some cases, notified bodies have been waiting several years for final reports from joint monitoring procedures.

Our proposal

- Add clear deadlines in Articles 1(30) and (35)(e) to be met by notifying authorities.

→ Proposal for amendments

9. Regulatory sandboxes: Separate regulatory sandboxes from conformity assessment procedures

The TÜV Association welcomes the proposal to establish regulatory sandboxes at national and Union level (Article 59(b)+(c) MDR, Article 54(b)+(c) IVDR). However, the participation within a regulatory sandbox can under no circumstances lead to a presumption of conformity. It should be made clear that a full conformity assessment, possibly involving a notified body, is still required before placing the product on the market – in the interest of patient safety and competitiveness.

Our proposal

- Clarify Articles 1(59) and 2(36) that a regulatory sandbox participation does not lead to a presumption of conformity.

→ Proposal for amendments

10. Further points

Conformity assessment of breakthrough devices and of orphan devices

We welcome the fact that the Commission lays down requirements for the conformity assessment of breakthrough devices and of orphan devices. In case of a confirmed breakthrough medical device or a medical device for rare conditions, the notified body involved must treat the conformity assessment of this medical device as a priority and, if necessary, carry out ongoing reviews in order to shorten the assessment periods.

It must be pointed out that such a requirement comes at the expense of other ongoing certification procedures. That must be taken into account when setting deadlines for certification procedures. A situation must not arise in which such requirements cause other certification procedures to fail, e.g. due to the expiry of deadlines. Nor must such requirements give rise to liability risks for notified bodies. That must be taken into account when setting deadlines for certification procedures in subsequent legal acts.

Mechanism for screening relevant sources of scientific and clinical data and post-market information

The increased exchange between notified bodies envisaged by the Commission is generally to be welcomed. Screening of *general* sources of scientific and clinical data can be divided between notified bodies and the results shared. Nevertheless, the screening of *relevant* sources of scientific and clinical data is the original task of the notified body itself. This also applies to post-market information by notified bodies relevant to the scope of their designation. Such tasks may not be completely transferred to other groups in view of the necessary qualifications that must be available in the bodies (the respective notified body has the necessary designation for this product/product group and thus the necessary expertise, this may not be the case for other groups) and liability issues.

In this context, it would be important that the competent authorities provide notified bodies with all the information and data to which only the competent authorities have access, not the notified bodies.

Missing definitions

A lot of definitions are missing, especially for “clinical management”, “condition”, “clinical outcome”, “similar device” and “rolling review”.

Amendment proposals

1. Notified body operations: Do not jeopardise core market economy principles

- Maintain subparagraphs 2, 3, 5, and 6 in Article 1(40).
- Back to recommendations in detail

No.	Article	Draft text of the COM proposal	Amendment proposal	Justification
1	1(40)	Article 50 Access to notified bodies and fees 1. Notified bodies shall establish lists of their fees for the conformity assessment activities that they carry out and shall make those lists publicly available. They shall notify the lists to the Commission, which shall make references to them available to the public on a dedicated website. *2. Notified bodies shall apply at least a 50 % fee reduction for manufacturers that are micro enterprises within the meaning of Recommendation 2003/361/EC and at least a 25 % fee reduction for small enterprises within the meaning of that Recommendation. They shall apply at least a 50 % fee reduction for manufacturers that apply for conformity assessment of an orphan device referred to in Article 52a (3). Notified bodies shall provide manufacturers that are micro or small enterprises within the meaning of Recommendation 2003/361/EC the possibility to defer the payment of fees until the relevant conformity assessment activity is finalised.* *3. The Commission, in consultation with the MDCG, may adopt*	Article 50 Access to notified bodies and fees 1. Notified bodies shall establish lists of their fees for the conformity assessment activities that they carry out and shall make those lists publicly available. They shall notify the lists to the Commission, which shall make references to them available to the public on a dedicated website. ~~*2. Notified bodies shall apply at least a 50 % fee reduction for manufacturers that are micro enterprises within the meaning of Recommendation 2003/361/EC and at least a 25 % fee reduction for small enterprises within the meaning of that Recommendation. They shall apply at least a 50 % fee reduction for manufacturers that apply for conformity assessment of an orphan device referred to in Article 52a (3). Notified bodies shall provide manufacturers that are micro or small enterprises within the meaning of Recommendation 2003/361/EC the possibility to defer the payment of fees until the relevant conformity assessment activity is finalised.*~~ ~~*3. The Commission, in consultation with the MDCG, may adopt*~~	Notified bodies are not authorities, but private companies. Therefore, they cannot be subject to the same requirements as authorities. If notified bodies cannot operate in an economically sustainable manner, they will no longer offer their services on the market, with serious consequences for manufacturers.

		implementing acts to specify the structure and level of the fees referred to in paragraph 1, taking into account the need to: *a. establish and maintain high standards of quality and safety of devices;* *b. ensure the availability of devices;* *c. protect the interests of micro, small or medium-sized enterprises within the meaning of Recommendation 2003/361/EC;* *d. support innovation and competitiveness.* **4.** Notified bodies shall ensure that manufacturers, which are micro, small or medium-sized enterprises within the meaning of Recommendation 2003/361/EC, have access to their conformity assessment activities in a manner that is not less favourable than the manner in which access is provided to other manufacturers. *5. Notified bodies shall deal with any request for conformity assessment activities from a manufacturer and, within 15 days of receipt of the request, inform the manufacturer accordingly.* *6. When duly justified in the interest of public health or patient health or safety, the authority responsible for notified bodies may instruct a notified body to accept a manufacturer's request for conformity assessment activities falling within that notified body's scope of designation.'*	~~*implementing acts to specify the structure and level of the fees referred to in paragraph 1, taking into account the need to:*~~ ~~*a. establish and maintain high standards of quality and safety of devices;*~~ ~~*b. ensure the availability of devices;*~~ ~~*c. protect the interests of micro, small or medium-sized enterprises within the meaning of Recommendation 2003/361/EC;*~~ ~~*d. support innovation and competitiveness.*~~ 4. Notified bodies shall ensure that manufacturers, which are micro, small or medium-sized enterprises within the meaning of Recommendation 2003/361/EC, have access to their conformity assessment activities in a manner that is not less favourable than the manner in which access is provided to other manufacturers. ~~*5. Notified bodies shall deal with any request for conformity assessment activities from a manufacturer and, within 15 days of receipt of the request, inform the manufacturer accordingly.*~~ ~~*6. When duly justified in the interest of public health or patient health or safety, the authority responsible for notified bodies may instruct a notified body to accept a manufacturer's request for conformity assessment activities falling within that notified body's scope of designation.'*~~	

2. Sample size: Do not reduce the sample size of technical documentations

- Article 1 (43) (a), Annex I (5) (q) (ii) and (7) (a) and (e), Annex II (5) (s) (i) (2) and (6) (a) and (e) of the Commission's proposal should be deleted.
- Define concrete requirements for sampling prior to issuing a QMS certificate and during surveillance after issuing the certificate.
- Back to recommendations in detail

No.	Article	Draft text of the COM proposal	Amendment proposal	Justification
2	1(43)(a)	Article 52 is amended as follows: (a) in paragraph 3, the following subparagraph is added: *a) in paragraph 3, the following subparagraph is added:* *'By way of derogation from the first subparagraph, class III devices that are well-established technology devices shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation of one representative device per generic device group.';*	Article 52 is amended as follows: (a) in paragraph 3, the following subparagraph is added: ~~*a) in paragraph 3, the following subparagraph is added:*~~ ~~*'By way of derogation from the first subparagraph, class III devices that are well-established technology devices shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation of one representative device per generic device group.';*~~	The frequency of sampling should not be reduced. The safety of products, patients, and users should not take a back seat to economic considerations.
3	Annex I (5)(q)(ii) Annex II (5)(s)(i)(2)	*the fourth indent is replaced by the following:* *'clearly identify, for class IIa and class IIb devices, the representative devices selected for the assessment of technical documentation as referred to in Annexes II and III,'*	~~*the fourth indent is replaced by the following:*~~ ~~*'clearly identify, for class IIa and class IIb devices, the representative devices selected for the assessment of technical documentation as referred to in Annexes II and III,'*~~	The frequency of sampling should not be reduced. The safety of products, patients, and users should not take a back seat to economic considerations.
4	Annex I (7)(a)	*In Section 2.3, the third and fourth paragraphs are replaced by the following:* *'Moreover, in the case of class IIa and class IIb devices, the quality management system assessment shall be accompanied by the*	~~*In Section 2.3, the third and fourth paragraphs are replaced by the following:*~~ ~~*'Moreover, in the case of class IIa and class IIb devices, the quality management system assessment shall be accompanied by the*~~	The frequency of sampling should not be reduced. The safety of products, patients, and users

		assessment of the technical documentation, as referred to in Annex II and III, as specified in Sections 4.3 to 4.8 for a representative device. *(...)*	~~*assessment of the technical documentation, as referred to in Annex II and III, as specified in Sections 4.3 to 4.8 for a representative device.*~~ *(...)* *delete entire section*	should not take a back seat to economic considerations.
5	Annex I (9)(aa) (new)	/	*In Annex XI, section 2.3, a fifth' and six' paragraph is added:* *Sampling prior to issuing a QMS certificate:* *For the sampling prior to issuing a QMS certificate, together with every surveillance audit, at least one representative sample of the EMDN level 3 code shall be subject to a full technical documentation assessment.* *Sampling during surveillance after issuing the certificate:* *For the sampling during surveillance, together with every surveillance audit, at least one representative sample of the EMDN level 3 code shall be subject to the technical documentation assessment, as long as the previous assessments did not cover the same product (Basic UDI-DI).* *In order to avoid unnecessary duplication of assessments, the depth of the surveillance assessments shall at least cover the post market surveillance aspects as well as Chapters I and II of Annex I of this regulation.*	Concrete requirements for sampling prior to issuing a QMS certificate and during surveillance after issuing the certificate are needed.
6	Annex I (7)(e)	*Section 3.5 is replaced by the following:* *In the case of class IIa and class IIb devices, and of class III devices that are well-established technology devices, during the surveillance assessment the notified body may include a 'for-*	~~*Section 3.5 is replaced by the following:*~~ ~~*In the case of class IIa and class IIb devices, and of class III devices that are well-established technology devices, during the surveillance assessment the notified body may include a 'for-*~~	The frequency of sampling should not be reduced. The safety of products, patients, and users

		cause' assessment of the technical documentation of representative devices where the notified body has identified potential concerns on the basis of post-market surveillance data or other duly justified grounds. *(...)*	~~*cause' assessment of the technical documentation of representative devices where the notified body has identified potential concerns on the basis of post-market surveillance data or other duly justified grounds.*~~ *(...)* *delete entire section*	should not take a back seat to economic considerations.
7	Annex II (6)(a)	*in Section 2.3., the third and fourth paragraphs are replaced by the following:* *'Moreover, in the case of class B and class C devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation, as referred to in Annexes II and III, as specified in Sections 4.3. to 4.8., for a representative device selected as follows:* *- for class B devices, one device;* *- for class C devices, one device per generic device group.* *(...)*	~~*in Section 2.3., the third and fourth paragraphs are replaced by the following:*~~ ~~*'Moreover, in the case of class B and class C devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation, as referred to in Annexes II and III, as specified in Sections 4.3. to 4.8., for a representative device selected as follows:*~~ ~~*- for class B devices, one device;*~~ ~~*- for class C devices, one device per generic device group.*~~ *(...)* *delete entire section*	The frequency of sampling should not be reduced. The safety of products, patients, and users should not take a back seat to economic considerations.
8	Annex II (8)(aa)(new)	/	In Annex XI, section 2.3, a fifth' and six' paragraph is added: *Sampling prior to issuing a QMS certificate:* *For the sampling prior to issuing a QMS certificate, together with every surveillance audit, at least one representative sample of the EMDN level 3 code shall be subject to a full technical documentation assessment.* *Sampling during surveillance after issuing the certificate:* *For the sampling during surveillance, together with every*	

			surveillance audit, at least one representative sample of the EMDN level 3 code shall be subject to the technical documentation assessment, as long as the previous assessments did not cover the same product (Basic UDI-DI). *In order to avoid unnecessary duplication of assessments, the depth of the surveillance assessments shall at least cover the post market surveillance aspects as well as Chapters I and II of Annex I of this regulation.*	
9	Annex II (6)(e)	*Section 3.5 is replaced by the following:* *In the case of class B and class C devices, during the surveillance assessment the notified body may include a 'for-cause' assessment of the technical documentation of representative devices where the notified body has identified potential concerns on the basis of post-market surveillance data or other duly justified grounds.*	~~*Section 3.5 is replaced by the following:*~~ ~~*In the case of class B and class C devices, during the surveillance assessment the notified body may include a 'for-cause' assessment of the technical documentation of representative devices where the notified body has identified potential concerns on the basis of post-market surveillance data or other duly justified grounds.*~~	The frequency of sampling should not be reduced. The safety of products, patients, and users should not take a back seat to economic considerations.

3. Unannounced audits: Do not reduce the scope and frequency of unannounced audits

- Maintain the original monitoring and assessment provisions by deleting Annex I (7)(d) and Annex II (6)(d)
- Back to recommendations in detail

No.	Article	Draft text of the COM proposal	Amendment proposal	Justification
10	Annex I (7)(d)	*(d) Section 3.4 is amended as follows:* *(i) the first paragraph is replaced by the following:* *'The notified body shall perform short-notice or unannounced audits on the site of the manufacturer and, where appropriate, of*	~~*(d) Section 3.4 is amended as follows:*~~ ~~*(i) the first paragraph is replaced by the following:*~~ ~~*'The notified body shall perform short-notice or unannounced audits on the site of the manufacturer and, where appropriate, of*~~	Unannounced audits should be maintained in the interests of patient safety. The number

		the manufacturer's suppliers and/or subcontractors when justified based on concerns related to post-market surveillance or vigilance data or at the request of a competent authority. The short-notice or unannounced audit may be combined with the periodic surveillance assessment referred to in Section 3.3. or be performed in addition to that surveillance assessment.'; *(...)*	~~*the manufacturer's suppliers and/or subcontractors when justified based on concerns related to post-market surveillance or vigilance data or at the request of a competent authority. The short-notice or unannounced audit may be combined with the periodic surveillance assessment referred to in Section 3.3. or be performed in addition to that surveillance assessment.';*~~ *(...) delete entire section*	of product tests can be reduced.
11	Annex II (6)(d)	*Section 3.4. is amended as follows:* *(i) the first paragraph is replaced by the following:* *'3.4. The notified body shall perform audits, at short notice or unannounced, on the site of the manufacturer and, where appropriate, the site of the manufacturer's suppliers and/or subcontractors, when justified based on concerns related to post-market surveillance or vigilance data or at the request of a competent authority. The short-notice or unannounced audit may be combined with the periodic surveillance assessment referred to in Section 3.3. or be performed in addition to that surveillance assessment.';* *(...)*	~~*Section 3.4. is amended as follows:*~~ ~~*(i) the first paragraph is replaced by the following:*~~ ~~*'3.4. The notified body shall perform audits, at short notice or unannounced, on the site of the manufacturer and, where appropriate, the site of the manufacturer's suppliers and/or subcontractors, when justified based on concerns related to post-market surveillance or vigilance data or at the request of a competent authority. The short-notice or unannounced audit may be combined with the periodic surveillance assessment referred to in Section 3.3. or be performed in addition to that surveillance assessment.';*~~ *(...) delete entire section*	Unannounced audits should be maintained in the interests of patient safety. The number of product tests can be reduced.

4. Surveillance audits: Do not reduce the frequency of surveillance audits and assessments

- Delete the requirement in Article 1(7)(c) and Article 2(6)(c) that provide for surveillance audits and assessments to be carried out every 24 months instead of every 12 months under certain conditions.
- Back to recommendations in detail

No.	Article	Draft text of the COM proposal	Amendment proposal	Justification
12	1(7)(c)	Section 3.3 is replaced by the following: 3.3 Notified bodies shall periodically carry out appropriate audits and assessments to make sure that the manufacturer in question applies the approved quality management system and the post-market surveillance plan. Those audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. On justified grounds, the audit may be conducted remotely instead of on-site. The notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with a surveillance audit report and, if a test has been carried out, with a test report. The notified body shall carry out the surveillance audits and assessments once every 12 months. ***However, where justified in light of the results of previous surveillance audits and assessments, and in the absence of any concerns resulting from data from post-market surveillance or vigilance, the notified body shall carry out the surveillance audits and assessments only once every 24 months.***	Section 3.3 is replaced by the following: 3.3 Notified bodies shall periodically carry out appropriate audits and assessments to make sure that the manufacturer in question applies the approved quality management system and the post-market surveillance plan. Those audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. On justified grounds, the audit may be conducted remotely instead of on-site. The notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with a surveillance audit report and, if a test has been carried out, with a test report. The notified body shall carry out the surveillance audits and assessments once every 12 months. ~~***However, where justified in light of the results of previous surveillance audits and assessments, and in the absence of any concerns resulting from data from post-market surveillance or vigilance, the notified body shall carry out the surveillance audits and assessments only once every 24 months.***~~	The requirement that, under certain conditions, surveillance audits and assessments should only be carried out every 24 months instead of every 12 months creates legal uncertainty and will lead to very different interpretations, as there are no specific requirements. Therefore, surveillance audits and assessments should continue to take place every 12 months in the interests of uniform requirements, a high level of monitoring.
13	2(6)(c)	Section 3.3 is replaced by the following:	Section 3.3 is replaced by the following:	The requirement that, under certain

		3.3 Notified bodies shall periodically carry out appropriate audits and assessments to make sure that the manufacturer in question applies the approved quality management system and the post-market surveillance plan. Those audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. On justified grounds, the audit may be conducted remotely instead of on-site. The notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with a surveillance audit report and, if a test has been carried out, with a test report. The notified body shall carry out the surveillance audits and assessments once every 12 months. ***However, where justified in light of the results of previous surveillance audits and assessments, and in the absence of any concerns resulting from data from post-market surveillance or vigilance, the notified body shall carry out the surveillance audits and assessments only once every 24 months.***	3.3 Notified bodies shall periodically carry out appropriate audits and assessments to make sure that the manufacturer in question applies the approved quality management system and the post-market surveillance plan. Those audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. On justified grounds, the audit may be conducted remotely instead of on-site. The notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with a surveillance audit report and, if a test has been carried out, with a test report. The notified body shall carry out the surveillance audits and assessments once every 12 months. ~~***However, where justified in light of the results of previous surveillance audits and assessments, and in the absence of any concerns resulting from data from post-market surveillance or vigilance, the notified body shall carry out the surveillance audits and assessments only once every 24 months.***~~	conditions, surveillance audits and assessments should only be carried out every 24 months instead of every 12 months creates legal uncertainty and will lead to very different interpretations, as there are no specific requirements. Therefore, surveillance audits and assessments should continue to take place every 12 months in the interests of uniform requirements, a high level of monitoring.

5. Class III devices and well-established technologies: Do not introduce unclear definitions

- Delete the definition of WET (delete Article 1(2)(e)).
- Establish a list of products falling under the WET definition by the EU Commission or make a binding decision by an expert panel.

- Do not reduce monitoring requirements for class III devices classified as WET, only allow facilitation measures provided for in Article 61(6), Article 1 (43) (a) should be deleted and Annex 1 (7) (e) should be adjusted.
- Back to recommendations in detail

No.	Article	Draft text of the COM proposal	Amendment proposal	Justification
14	1(2)(e)	**(72) 'well-established technology device' means a device that belongs to a generic device group, which fulfils the following criteria:** **(a) it has simple, common and stable design;** **(b) it has not been associated with safety issues in the past;** **(c) it has well-known clinical performance characteristics and comprises standard of care devices with little evolution in indications and the state of the art;** **(d) it has a long history on the Union market;**	~~(72) 'well-established technology device' means a device that belongs to a generic device group, which fulfils the following criteria:~~ ~~(a) it has simple, common and stable design;~~ ~~(b) it has not been associated with safety issues in the past;~~ ~~(c) it has well-known clinical performance characteristics and comprises standard of care devices with little evolution in indications and the state of the art;~~ ~~(d) it has a long history on the Union market;~~	The definition leaves a lot of room for interpretation.
15	1(3)	***1. The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend the definition of well-established technology device set out in Article 2, point (72), in the light of technical and scientific progress and taking into account definitions agreed at Union and international level.*** ***2.*** The Commission may, by means of implementing acts, draw up ***non-exhaustive*** lists of devices ***that fall under, or of devices that do not fall under the definition of*** well-established technology ***device in Article 2, point (72)***. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).	~~*1. The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend the definition of well-established technology device set out in Article 2, point (72), in the light of technical and scientific progress and taking into account definitions agreed at Union and international level.*~~ ~~*2.*~~ The Commission may, by means of implementing acts, draw up ~~*non-exhaustive*~~ lists of devices ~~*that fall under, or of devices that do not fall under the definition of*~~ well-established technology ~~*device in Article 2, point (72)*~~. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).	The definition leaves a lot of room for interpretation. A list of all products that are considered WET is clearer.
16	1(43)(a)	***(a) in paragraph 3, the following subparagraph is added:*** ***'By way of derogation from the first subparagraph, class III devices that are well-established technology devices shall be subject to a conformity assessment as specified in Chapters I and***	~~*(a) in paragraph 3, the following subparagraph is added:*~~ ~~*'By way of derogation from the first subparagraph, class III devices that are well-established technology devices shall be subject to a conformity assessment as specified in Chapters I and*~~	With view to patient safety class III devices should not benefit from

		III of Annex IX, including an assessment of the technical documentation of one representative device per generic device group.'	~~*III of Annex IX, including an assessment of the technical documentation of one representative device per generic device group.'*~~	reduced monitoring requirements.
17	1(7)(e)	(e) Section 3.5 is replaced by the following: '3.5 In the case of class IIa and class IIb devices*, and of class III devices that are well-established technology devices,* during the surveillance assessment the notified body may include a 'for-cause' assessment of the technical documentation of representative devices where the notified body has identified potential concerns on the basis of post-market surveillance data or other duly justified grounds. In the case of class III devices*, with the exception of well-established technology devices,* the surveillance assessment shall also include a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.';	(e) Section 3.5 is replaced by the following: '3.5 In the case of class IIa and class IIb devices~~*, and of class III devices that are well-established technology devices,*~~ during the surveillance assessment the notified body may include a 'for-cause' assessment of the technical documentation of representative devices where the notified body has identified potential concerns on the basis of post-market surveillance data or other duly justified grounds. In the case of class III devices~~*, with the exception of well-established technology devices,*~~ the surveillance assessment shall also include a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.';	With view to patient safety class III devices should not benefit from reduced monitoring requirements.
18	1(45a) new	/	*Article 52 c* *1. Upon a duly substantiated request by a manufacturer or a notified body, an expert panel referred to in Article 106 shall provide a decision within 30 days as to whether device is a well-established technology.* *2. The decision shall be published on a dedicated website without disclosing any confidential information as referred to in Article 109.*	A list of all products that are considered WETs needs to be drawn up by the European Commission or a binding decision needs to be made by an expert panel.

			3. The decision shall be binding for the manufacturer and the notified body. *4. Only devices listed in accordance with Article 3 or for which a decision according to paragraph 1 of this Article is available are considered to be a well-established technology.*	

6. Classification requirements: Do not downgrade classification requirements

- Delete the possibility to not involve a notified body for class Ir medical devices in Article 1 (43) (e) (ii).
- Do not downgrade classification from class III to class Ir, delete Annex I (6) (c) and (d)
- Do not change the definition of medical device, delete Article 1 (2) (a).
- Back to recommendations in detail

No.	Article	Draft text of the COM proposal	Amendment proposal	Justification
19	1(43)(e)(ii)	*Where the manufacturer of class I reusable surgical instruments has applied harmonised standards or CS covering all relevant aspects referred to in the first subparagraph, point (c), the involvement of a notified body is not required.*	~~*Where the manufacturer of class I reusable surgical instruments has applied harmonised standards or CS covering all relevant aspects referred to in the first subparagraph, point (c), the involvement of a notified body is not required.*~~	Do not reduce requirements for class Ir.
20	Annex I (6)(c) & (d)	*(c) in Section 5.2, the second indent is replaced by the following:* *– 'are reusable surgical instruments regardless of the body part with which they come into contact, in which case they are classified as class I;';* *(d) in Section 5.3, the following indent is added:* *– 'are reusable surgical instruments regardless of the body part with which they come into contact, in which case they are classified as class I;'*	~~*(c) in Section 5.2, the second indent is replaced by the following:*~~ ~~*– 'are reusable surgical instruments regardless of the body part with which they come into contact, in which case they are classified as class I;';*~~ ~~*(d) in Section 5.3, the following indent is added:*~~ ~~*– 'are reusable surgical instruments regardless of the body part with which they come into contact, in which case they are classified as class I;'*~~	not downgrade classification (from class III to class Ir).

21	2(29)(h)	*(h) in paragraph 10, the second subparagraph is deleted;*	~~*(h) in paragraph 10, the second subparagraph is deleted;*~~	Do not reduce relevant safety requirements for IVDs.

7. Dispute settlement: Do not establish unsuitable procedures

- Delete Article 1(27)(a).
- Back to recommendations in detail

No.	Article	Draft text of the COM proposal	Amendment proposal	Justification
22	1(27)(a)	*The following paragraph 6a is inserted:* *6a. Without prejudice to other administrative or judicial remedies, a manufacturer or notified body may raise with the authority responsible for notified bodies, in a duly substantiated manner, any unresolved dispute arising from the application of the requirements set out in Annex VII and the involvement of a notified body in the conformity assessment in accordance with Article 52 and Annexes IX, X and XI.* (...)	~~*The following paragraph 6a is inserted:*~~ ~~*6a. Without prejudice to other administrative or judicial remedies, a manufacturer or notified body may raise with the authority responsible for notified bodies, in a duly substantiated manner, any unresolved dispute arising from the application of the requirements set out in Annex VII and the involvement of a notified body in the conformity assessment in accordance with Article 52 and Annexes IX, X and XI.*~~ *(...) delete entire section*	The procedure does not add any value, as it is not binding on either manufacturers or notified bodies. Furthermore, it completely disregards liability issues arising from the relevant decisions of the authorities. In case of doubt, such a procedure only delays ongoing certification procedures.

8. Timelines: Introduce clear timelines for every step of the notification procedure

- Add clear deadlines in Articles 1(30) and (35)(e) to be met by notifying authorities.
- Back to recommendations in detail

No.	Article	Draft text of the COM proposal	Amendment proposal	Justification
23	1(30)	[...] 6. Unless the application is rejected, the joint assessment team shall plan and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or subcontractor, located inside or outside the Union, that is to be involved in the conformity assessment process. Where an on-site assessment of the applicant body, a subsidiary or a subcontractor is temporarily impossible or impracticable due to exceptional circumstances, the joint assessment team may decide to carry out the assessment by other appropriate means. At the end of the on-site assessment, the joint assessment team shall list for the applicant conformity assessment body any noncompliances resulting from the assessment and summarise the assessment by the joint assessment team. [...] 11. The joint assessment team shall submit its final assessment report to the MCDG ***without undue delay***.	[...] 6. Unless the application is rejected, the joint assessment team shall plan and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or subcontractor, located inside or outside the Union, that is to be involved in the conformity assessment process ***within 90 days***. Where an on-site assessment of the applicant body, a subsidiary or a subcontractor is temporarily impossible or impracticable due to exceptional circumstances, the joint assessment team may decide to carry out the assessment by other appropriate means. At the end of the on-site assessment, the joint assessment team shall list for the applicant conformity assessment body any noncompliances resulting from the assessment and summarise the assessment by the joint assessment team. [...] 11. The joint assessment team shall submit its final assessment report to the MCDG ***within 15 days***.	Although the MDR and IVDR have led to a certain degree of harmonization of the designation procedures, there is still a long way to go before uniform procedures and requirements are achieved in practice. However, in order to create a level playing field and faster procedures, the measures must go even further. Clear timelines are needs.

		Based on the findings of the final assessment report, the authority responsible for notified bodies shall submit to the MDCG a draft decision on the designation of the notified body or reject the application. 12. Within 21 days of receipt of the draft decision on the designation referred to in paragraph 11, the MDCG shall issue a recommendation with regard to the envisaged designation, which the authority responsible for notified bodies shall duly take into consideration for its final decision on the designation of the notified body. That 21-day period may be extended once for a further 21 days on justified grounds. Where the authority responsible for notified bodies does not agree with the recommendation of the MDCG, it shall submit to the MDCG a duly justified request to reconsider its recommendation. Within 30 days of receipt of that request, the MDCG shall either confirm its recommendation or issue a new recommendation. 13. Where no agreement can be reached between the MDCG and the authority responsible for notified bodies, either party may refer the matter to the Commission. Within ***180*** days of receipt of the referral, the Commission shall, after consulting the MDCG, the authority responsible for notified bodies and, where necessary, the applicant conformity assessment body concerned, evaluate the draft decision on the designation and decide, by means of implementing act, whether or not the draft designation is justified.	Based on the findings of the final assessment report, the authority responsible for notified bodies shall submit to the MDCG a draft decision on the designation of the notified body or reject the application ***within 15 days***. 12. Within 21 days of receipt of the draft decision on the designation referred to in paragraph 11, the MDCG shall issue a recommendation with regard to the envisaged designation, which the authority responsible for notified bodies shall duly take into consideration for its final decision on the designation of the notified body. That 21-day period may be extended once for a further 21 days on justified grounds. Where the authority responsible for notified bodies does not agree with the recommendation of the MDCG, it shall submit to the MDCG a duly justified request to reconsider its recommendation ***within this period***. Within 30 days of receipt of that request, the MDCG shall either confirm its recommendation or issue a new recommendation. 13. Where no agreement can be reached between the MDCG and the authority responsible for notified bodies, either party may refer the matter to the Commission. Within ***120*** days of receipt of the referral, the Commission shall, after consulting the MDCG, the authority responsible for notified bodies and, where necessary, the applicant conformity assessment body concerned, evaluate the draft decision on the designation and decide, by means of implementing act, whether or not the draft designation is justified.	

24	1(35)(e)	[...] 4b. At the end of any assessment carried out pursuant to paragraph 4 or 4a, the authority responsible for notified bodies or the joint assessment team, as applicable, shall inform the notified body about any non-compliances resulting from the assessment and summarise their assessment. Where non-compliances have been identified, the notified body shall submit a proposed corrective and preventive action plan to address the non-compliances. That plan shall indicate the root cause of the identified non-compliances and shall include a timeframe for implementation of the actions set out therein. The authority responsible for notified bodies or the joint assessment team, as applicable, shall assess whether the non-compliances identified during the assessment have been appropriately addressed in the plan referred to in the second subparagraph and, where necessary, provide any comments on the plan to the notified body, including requests for further clarification and modifications. The notified body and the authority or the joint assessment team, as applicable, shall endeavour to agree on a final corrective and preventive action plan in due course. 4c. After receipt of the final corrective and preventive action plan, or where the authority responsible for notified bodies or the joint assessment team, as applicable, have not identified non-compliances or conclude that no agreement on a final plan has been reached, the authority or the joint assessment team, as applicable, shall draw up their final monitoring report which shall include the result of the assessment and, where applicable, conclusions	[...] 4b. At the end of any assessment carried out pursuant to paragraph 4 or 4a, the authority responsible for notified bodies or the joint assessment team, as applicable, shall inform the notified body about any non-compliances resulting from the assessment and summarise their assessment ***within 20 days***. Where non-compliances have been identified, the notified body shall submit a proposed corrective and preventive action plan to address the non-compliances. That plan shall indicate the root cause of the identified non-compliances and shall include a timeframe for implementation of the actions set out therein. The authority responsible for notified bodies or the joint assessment team, as applicable, shall assess whether the non-compliances identified during the assessment have been appropriately addressed in the plan referred to in the second subparagraph and, where necessary, provide any comments on the plan to the notified body, including requests for further clarification and modifications ***within 30 days***. The notified body and the authority or the joint assessment team, as applicable, shall endeavour to agree on a final corrective and preventive action plan in due course. 4c. After receipt of the final corrective and preventive action plan, or where the authority responsible for notified bodies or the joint assessment team, as applicable, have not identified non-compliances or conclude that no agreement on a final plan has been reached, the authority or the joint assessment team, as applicable, shall draw up their final monitoring report ***within 30 days*** which	Although the MDR and IVDR have led to a certain degree of harmonization of the designation procedures, there is still a long way to go before uniform procedures and requirements are achieved in practice. However, in order to create a level playing field and faster procedures, the measures must go even further. Clear timelines are needs.

		regarding the corrective and preventive action plan and, where applicable, any recommendations regarding the notified body's designation. The authority responsible for notified bodies or the joint assessment team, as applicable, shall submit their final monitoring report to the MDCG ***without undue delay***. The authority responsible for notified bodies shall monitor the implementation of the corrective and preventive action plan by the notified body, as appropriate. Where the final monitoring report concludes that the notified body no longer meets the requirements set out in this Regulation, or where the notified body fails to implement the corrective and preventive action plan, the authority responsible for notified bodies shall follow the procedure set out in Article 46(4).'	shall include the result of the assessment and, where applicable, conclusions regarding the corrective and preventive action plan and, where applicable, any recommendations regarding the notified body's designation. The authority responsible for notified bodies or the joint assessment team, as applicable, shall submit their final monitoring report to the MDCG ***within 10 days***. The authority responsible for notified bodies shall monitor the implementation of the corrective and preventive action plan by the notified body, as appropriate. Where the final monitoring report concludes that the notified body no longer meets the requirements set out in this Regulation, or where the notified body fails to implement the corrective and preventive action plan, the authority responsible for notified bodies shall follow the procedure set out in Article 46(4).'	

9. Regulatory sandboxes: Separate regulatory sandboxes from conformity assessment procedures

- Clarify Articles 1(59) and 2(36) that a regulatory sandbox participation does not lead to a presumption of conformity.
- Back to recommendations in detail

No.	Article	Draft text of the COM proposal	Amendment proposal	Justification
25	1(50)	[...]	Article 59(b) [...] ***8. Participation in a regulatory sandbox does not mean that the requirements regarding conformity assessment under this***	In the interests of patient safety, it must be made clear that all products

			Regulation are deemed to have been fulfilled. […] Article 59(c) […] ***6. Participation in a regulatory sandbox does not mean that the requirements regarding conformity assessment under this Regulation are deemed to have been fulfilled.***	must always meet the same requirements and undergo the same procedures.
26	2(36)	[…]	Article 54(b) […] ***8. Participation in a regulatory sandbox does not mean that the requirements regarding conformity assessment under this Regulation are deemed to have been fulfilled.*** […] Article 59(c) […] ***6. Participation in a regulatory sandbox does not mean that the requirements regarding conformity assessment under this Regulation are deemed to have been fulfilled.***	In the interests of patient safety, it must be made clear that all products must always meet the same requirements and undergo the same procedures.

Annex I - MDR: Overview on involvement into the conformity assessment procedures from the initial certification assessments to continuous surveillance activities

marked in red = reduction of involvement of notified bodies below MDD/AIMDD
marked in orange = reduction of involvement of notified bodies below current MDR / down to level of MDD/AIMDD
marked in yellow = reduction of involvement of notified bodies below current MDR and MDD/AIMDD possible
TD = technical documentation; NB = notified body, WET = well-established technologies, PSUR = periodic safety update report
Back to general remarks

<table>
<tr><td></td><td>Class</td><td colspan="3">III</td><td colspan="5">IIb</td><td colspan="3">IIa</td><td colspan="3">I</td></tr>
<tr><td></td><td>specification</td><td>Implantable</td><td>Non implantable</td><td>WET, definition with unclear parameters</td><td>Implantable</td><td>Implantable WET</td><td>Implantable EXEMPTED</td><td>Non implantable</td><td>Non implantable WET</td><td>Implantable</td><td>Implantable WET</td><td>Non implantable (WET / no-WET)</td><td>sterile condition</td><td colspan="2">reusable surgical instruments</td><td>measuring function</td></tr>
<tr><td rowspan="3">initial assessment TD</td><td>Current MDR</td><td colspan="3" rowspan="2">every device</td><td colspan="2">every device</td><td colspan="3">systematic TD sampling on representative basis (4th level EMDN)</td><td colspan="3" rowspan="2">systematic TD sampling on representative basis (MDA/MDN code)</td><td rowspan="3">limited to sterile aspects (part of audit onsite/offsite)</td><td colspan="2">limited to reprocessing aspects (part of audit onsite/offsite)</td><td rowspan="3">limited to measuring aspects (part of audit onsite/offsite)</td></tr>
<tr><td>MDD</td><td colspan="5">systematic TD sampling on representative basis/GMDN</td><td colspan="2">N/A</td></tr>
<tr><td>Proposal MDR</td><td>every device</td><td colspan="2">one device on representative basis (4th level EMDN)</td><td>every device</td><td>one device on representative basis (4th level EMDN)</td><td colspan="2">one device on representative basis (4th level EMDN)</td><td>one device on representative basis (MDA/MDN code)</td><td colspan="3">one device on representative basis (MDA/MDN code)</td><td>limited to reprocessing aspects (part of audit onsite/offsite) - when no self-declaration</td><td>N/A when self-declaration</td></tr>
<tr><td rowspan="3">IX, II Cert [11]</td><td>Current MDR</td><td colspan="3" rowspan="2">YES</td><td colspan="2">YES</td><td colspan="3">NO</td><td colspan="3" rowspan="3">N/A</td><td colspan="3" rowspan="3">N/A</td></tr>
<tr><td>MDD</td><td colspan="5">NO</td></tr>
<tr><td>Proposal MDR</td><td>YES</td><td colspan="2">NO</td><td>YES</td><td>NO</td><td colspan="3">NO</td></tr>
<tr><td rowspan="2">surveillance assessment</td><td>Current MDR</td><td colspan="3">auditing annually;
unannounced audit once in 5 years;
5-year recertification</td><td colspan="2">auditing annually;
unannounced audit once in 5 years;
5-year recertification</td><td colspan="3">auditing annually;
unannounced audit once in 5 years;
systematic TD sampling on representative basis (4th level EMDN);
5-year recertification cycle for QMS
at least 15% of devices from each category and from each generic device group covered in the certificate will be sampled during its validity (5 years) of the certificate [12]</td><td colspan="3">auditing annually;
unannounced audit once in 5 years;
systematic TD sampling on representative basis (MDA/MDN code);
15% of devices from each category and from each generic device group covered in the certificate will be sampled during its validity (5 years) of the certificate[12]</td><td colspan="3">auditing annually</td></tr>
<tr><td>MDD</td><td colspan="3">auditing annually;
unannounced audits possible</td><td colspan="5">auditing annually;
systematic TD sampling on representative basis/GMDN
5-year recertification cycle for QMS;
unannounced audits possible</td><td colspan="3">auditing annually;
systematic TD sampling on representative basis/MD code;
unannounced audits possible</td><td>auditing annually</td><td colspan="2">N/A</td><td>auditing annually</td></tr>
</table>

[11] Assessment of the technical documentation according to Annex IX, Chapter 2 MDR
[12] MDCG 2019-13 Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation

	Proposal MDR	auditing annually / every two years unannounced auditing ONLY on cause	auditing annually / every two years; unannounced auditing only on cause; 'for-cause' assessment of the TD of representative devices where the NB has identified potential concerns on the basis of post-market surveillance data or other duly justified grounds	auditing annually / every two years unannounced auditing ONLY on cause	auditing annually / every two years; unannounced auditing only on cause; 'for-cause' assessment of the TD of representative devices where the NB has identified potential concerns on the basis of post-market surveillance data or other duly justified grounds		auditing annually / every two years; unannounced auditing only on cause; 'for-cause' assessment of the TD of representative devices where the NB has identified potential concerns on the basis of post-market surveillance data or other duly justified grounds		auditing annually / every two years	N/A when self-declaration	auditing annually / every two years	
SSCP	Current MDR	YES		YES		N/A	YES	N/A	N/A			
	MDD	N/A		N/A			N/A					
	Proposal MDR	YES	NO	YES	NO	N/A	NO	N/A				
PSUR	Current MDR – Manufacturers DCP	annually		annually			every 2 years		N/A			
	Current MDR – NB review	annually through EUDAMED by NB		annually through EUDAMED by NB		make available upon request	through EUDAMED by NB	make available upon request				
	MDD	N/A		N/A			N/A					
	Proposal MDR - Manufacturers DCP	one year after certification then every two years	when necessary	one year after certification then every two years	when necessary		when necessary					
	Proposal MDR - NB review	through EUDAMED by NB in the first year and then every 2 years during surveillance assessment (auditing)	no NB standalone PSUR Review only when on cause individually or as part of the TD	through EUDAMED by NB in the first year and then every 2 years during surveillance assessment (auditing)	no NB standalone PSUR; Review only when on cause individual or as part of the TD		no NB standalone PSUR Review only when on cause individual or as part of the TD					
Recertification	Current MDR	YES: TD / QMS Recertification		YES: TD / QMS Recertification		YES: QMS Certificate	YES: QMS Certificate		YES: QMS Certificate			
	MDD			YES: QMS Recertification			YES: QMS Recertification		YES: QMS Recertification	N/A		YES: QMS Recertification
	Proposal MDR	no recertification (TD / QM) -> Periodic Review?		no recertification (TD / QMS) -> Periodic Review?		no recertification (QMS) -> Periodic Review?	no recertification (QMS) -> Periodic Review?		no recertification (QMS) -> Periodic Review?	no recertification (QMS) -> Periodic Review?	N/A when self-declaration	no recertification (QMS) -> Periodic Review?
Implant Card	Current MDR	YES		YES		NO	YES	N/A	N/A			
	MDD	N/A		N/A			N/A					
	Proposal MDR	YES	NO	YES	NO	NO	YES	NO	N/A			
serious incident[13]	Current MDR	15 days										
	MDD	30 days										
	Proposal MDR	30 days										

[13] reporting serious incidents Art. 87 (3) MDR

Annex II – IVDR: Overview on involvement into the conformity assessment procedures from the initial certification assessments to continuous surveillance activities

Comparison IVDD / IVDR / Proposal IVDR:

marked in red = reduction of involvement of notified bodies below IVDD
marked in orange = reduction of involvement of notified bodies below current IVDR / down to level of IVDD
marked in yellow = reduction of involvement of notified bodies below current IVDR and IVDD possible
TD = technical documentation, QMS = quality management system, NB = notified body, PMS = post-market surveillance, PMPF = Post-Market Performance Follow-up¸ PSUR = periodic safety update report , SSP = summary of safety and performance, ST = self-testing, NPT = near patient testing, CDx = companion diagnostic, EURL = EU reference laboratories
Back to general remarks

Aspect	IVDD List A	IVDR Class D	IVDR Class D (Proposal IVDR)
QMS Assessment	annual surveillance audit, 5-year certification cycle	annual surveillance audit, 5-year certification cycle	once every 12 months, however, options for once every 24 months
Unannounced audit	possible	every 5 years	only on cause
Technical documentation	full TD review	full TD review incl. PMS & PMPF	full TD review incl. PMS & PMPF
Certificate validity	time-limited max. five years	time-limited max. 5 years	unlimited (limitation by NB when constraints)
Certificate renewal	every five years	every five years	no renewal, replaced by periodic review
Reference lab/EURL involvement	performance evaluation review	performance evaluation review + performance verification	performance evaluation review + Performance verification
Batch testing	every batch	every batch	every batch
PMS requirements	minimal	annual PSUR Evaluation after certification	PSUR review one year after certification then every two years
Summary of safety and performance	N/A	SSP validation by NB initial and when updated	no SSP Validation by NB

Aspect	IVDD List B	IVDR Class B/C	IVDR Class B/C (Proposal IVDR)
QMS Assessment	5-year certification cycle, annual surveillance audit	5-year certification cycle, annual audit	once every 12 months, however, options for once every 24 months
Unannounced audit	every 5 years	every 5 years	only on cause
Initial - Technical documentation based on sampling	initial TD per IVDD NBOG code	1 Class B device (Basic UDI-DI) per each device categories 1 Class C device (Basic UDI-DI) per each generic device group	only 1 device for the entire Class B scope - no differentiation of categories 1 Class C device per each generic device group
Surveillance - Technical documentation based on sampling	1 device for minimum one NBOG code per year	5-15% of total Basic UDI-DIs: min. 1 Class B BUDI per each device category min. 1 Class C BUDI per each generic device group	no systematic sampling of TDs, for cause review only
Certificate validity	time-limited max. 5 years	time-limited max. 5 years	unlimited (limitation by NB when constraints)
Certificate renewal	every five years	every five years	unlimited (limitation by NB when constraints)

Comparison IVDR / Proposal IVDR:

marked in orange = reduction of involvement of notified bodies below current IVDR / down to level of IVDD
marked in yellow = reduction of involvement of notified bodies below current IVDR possible

	Class	Class A sterile	Class B	Class B - NPT	Class B - ST	Class C	Class C - NPT	Class C - ST, CDx	Class D
		Assessment of sterility aspects per sterilization method	TD assessment on representative basis	Assessment of TD for every product	Assessment of TD for every product	TD assessment on representative basis	Assessment of TD for every product	Assessment of TD for every product	Assessment of TD for every product
Initial Certification	IVDR	All	1 device per device category (IVR code)	100% TD review	100% TD review	1 device per generic device group (EMDN L3+ IVP)	100% TD review	100% TD review	100% TD review
	Proposal IVDR	N/A	1 device for class B	1 device for class B			1 device per generic device group (EMDN L3+ IVP)		
First Certification Cycle	IVDR	All	5% Basic UDI-DIs, min. 1 BUDI per device category	Renewal every 5 year	Renewal every 5 year	5% Basic UDI-DIs, min. 1 BUDI per generic device group	Renewal every 5 year	Renewal every 5 year	Renewal every 5 year
	Proposal IVDR	N/A	for cause assessment	for cause assessment	Periodic reviews	for cause assessment	for cause assessment	Periodic reviews	Periodic reviews
Subsequent Certification Cycles	IVDR	All	5-15% Basic UDI-DIs, min. 1 BUDI per device category	Renewal every 5 year	Renewal every 5 year	5-15% Basic UDI-DIs, min. 1 BUDI per generic device group per generic device group	Renewal every 5 year	Renewal every 5 year	Renewal every 5 year
	Proposal IVDR	N/A	for cause assessment	for cause assessment	Periodic reviews	for cause assessment	for cause assessment	Periodic reviews	Periodic reviews
PSUR evaluation	IVDR	N/A	N/A	N/A	N/A	made available to the NB	made available to the NB	made available to the NB	PSUR review annually
	Proposal IVDR								PSUR review one year after certification then every two year
SSP validation	IVDR	N/A	N/A	N/A	N/A	Either during TD review or during certification cycle according to SSP validation plan	During initial certification and when updated for each device	During initial certification and when updated for each device	During initial certification and when updated for each device
	Proposal IVDR					N/A	N/A	Reviewed as part of TD assessment only	Reviewed as part of TD assessment only
Annual surveillance audit (Annex IX Ch. I / Annex XI)	IVDR	at least once every 12 months							
	Proposal IVDR	Once every 12 months, however, options for once every 24 months							
Unannounced audit (Annex IX Ch. I / Annex XI)	IVDR	at least once every 5 years							
	Proposal IVDR	only for cause							
Art. 82(3) reporting any serious incidents	IVDR	15 days							
	Proposal IVDR	30 days							

Your contacts

Mark Küller
Head of Medical Devices
Email: mark.kueller@tuev-verband.de
Phone: +49 30 760095 435

Johannes Kröhnert
Head of Brussels Office
Email: johannes.kroehnert@tuev-verband.de
Phone: +49 30 760095 500 / +32 471 79 33 00

As TÜV Association, we represent the policy interests of the TÜV assessment organisations and foster the professional exchange between our members. We are committed to the technical safety, digital security and sustainability of products, systems and services. Universally applicable standards, independent assessments and qualified training form the basis. Our goal is to maintain the high level of technical safety, to build trust in our digital world and to preserve our livelihoods. To this end, we are in regular exchanges with policymakers, authorities, the media, companies and consumers.

Published by
TÜV-Verband e. V.
Friedrichstraße 136
10117 Berlin

Phone: +49 30 760095-400
Email: berlin@tuev-verband.de
www.tuev-verband.de/en