Joint Opinion of D-A-CH region industry associations: Urgent need for legal measures to facilitate MDR/IVDR implementation through simplification.

Supplement to
Annex I | D-A-CH region industry associations proposals for urgent measures to decrease bureaucracy and facilitate MDR/IVDR implementation (15.11.2024***)***

July 25, 2025

No. 1

Issue and current requirement:

Art. 10a

Qualification of bureaucratic issue:

MDR and IVDR requirement

Reporting of discontinuation

Explanation:

The wording of Art. 10a MDR is very broad. Taken literally, it would introduce a massive administrative burden on all manufacturers of medical devices on the EU market, disproportionate to the effect the article seeks to achieve.

Rationale:

Appropriate measures are required in response to the respective information. Yet, countermeasures by the competent authorities were not standardised in the course of the introduction of Art. 10a MDR. The competent authorities to which the information is reported lack powers to ensure supply, for example in the form of replacement purchases by the Member States. The Commission's Q&A does also not address any countermeasures.

Resolution:

Proposed instrument / legal basis for resolution:

Delete Art. 10a

Description:

Key principle:

1, 2, 3

No. 2

Issue and current requirement:

Article 87(3)

Qualification of bureaucratic issue:

MDR requirement

Excessive reporting of false positives for potentially serious incidents

Explanation:

For a potential serious incident, where nobody was actually harmed but where there is only a suspicion that the product could pose a risk, the MDR reduced the notification period

from 30 days (MDD) to 15 days. As the investigation of such cases often takes longer than 15 days (e.g. if a device must be sent to the manufacturer for analysis), manufacturers are obliged to report many cases of potential incidents many of which later turn out to be unsubstantiated.

This is exasperated by the fact that the MDR does not really address the likelihood of harm in the definition of serious incident ("might have led or might lead") which can lead to the reporting of events with only insignificant risk.

Rationale:

The short notification period in unconfirmed cases has no safety benefits but leads to a high volume of false-positive or unsubstantiated reports, burdening both manufacturers and competent authorities, while diluting the focus on high-risk events. For incidents with real harm, appropriate a shorter notification period (10 days) is already in place.

Returning to a 30-day reporting obligation for cases without realized harm would be appropriate, at least for cases where the risk is low. 30 day is also a timeframe that is used in many other jurisdictions without there being any evidence in the literature that this has any disadvantage.

The 15 days notification period should be retained for cases with high risk i.e. when the likelihood of severe harm is high.

A graduated approach would align with the risk-based vigilance system laid out in Articles 83 to 89 of the MDR, support more targeted, higher-quality reporting improve the usefulness and signal value of vigilance data and would be in line with Recitals 5, 59 and 61 of the MDR, which call for a vigilance system that is effective, proportionate, and focused on real safety signals, while avoiding unnecessary public concern and administrative burden.

Resolution:

Proposed instrument / legal basis for resolution:

Change MDR Article 87 (3) to introduce a risk-based, tiered reporting timeline:

A shorter deadline (15 days) remains in place for events with a high probability of serious harm under normal or foreseeable conditions.

A longer deadline (30 days) allows time for a substantiated assessment in cases with low or uncertain risk and no actual harm.

Description:

Proposed Text: 3. *Manufacturers shall report any serious incident as referred to in point (a) of paragraph 1 immediately after they have established the causal relationship between that incident and their device or that such causal relationship is reasonably possible and not later than 30 days after they become aware of the incident. However, where it appears likely that an identical or similar incident could lead to death or serious deterioration of health under normal or foreseeable*

conditions of use, the manufacturer shall submit the report not later than 15 days after becoming aware of the incident.

Key principle:

1, 2, 3

No. 3

Issue and current requirement:

Clinical evaluation updates

Qualification of bureaucratic issue:

MDR requirement

Parallel PMS- and clinical evaluation update processes lead to redundant work

Explanation:

Currently, manufacturers of legacy and well-established devices need to update the clinical evaluation throughout the life cycle of the device concerned with clinical data obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84.

However, the PMS/ PMCF process should be proportionate to the expectable risk, and capable of being automated and statistics driven to ensure that costs for compliance are kept at reasonable levels and processes are appropriate for the devices concerned.

Article 61 MDR shall be amended to eliminate the requirement for a Clinical Evaluation Plan (CEP)

and Clinical Evaluation Report (CER) update for legacy and well-established devices in Classes I, I* (Ir, Is, Im), and selected nonactive Class IIa devices with a proven safety record.

PMS and PMCF should be about detecting signals relevant to PMS and PMCF. Targeted clinical safety evaluation will perform better than periodic clinical evaluation updates, especially for legacy and well- established devices.

Rationale:

According to MEDDEV 2.7.1 rev. 4 clinical evaluation shall be actively updated every 2 to 5 years if the device is not expected to carry significant risks and is well established.

However, updates of clinical evaluation reports are extremely time consuming and costly process, which need to be conducted also if there are no relevant changes to report from PMS and PMCF activities.

We propose a clinical safety based “Legacy Safety Summary File” instead for the monitoring of the compliance with state of the art and of clinical safety.

This can be implemented by means of a small amendment to Article 61 (11) MDR or could be done by means of an implementing act based on article 61 (13) MDR, supported by MDCG guidance.

Resolution:

Proposed instrument / legal basis for resolution:

Amendment to article 61 (11) 1st paragraph MDR.

Amend MEDDEV 2.7.1rev. 4.

Description:

Article 61 (11) 1st paragraph is amended as follows:

For legacy and well-established devices, subsequent to an initial clinical evaluation, clinical evaluation documentation updates are not required.

Manufacturers shall maintain a Legacy Safety Summary File containing:

a. Product description and classification.

b. Risk management report (ISO 14971).

c. Post-market surveillance (PMS) summary for ≥ 5 years.

d. Declaration of conformity with relevant standards.

e. Test reports (biocompatibility, mechanical, reprocessing/sterilisation as applicable).

f. State-of-the-art alignment and acceptance criteria for clinical safety. The Legacy Safety Summary File shall be updated every 5 years on the basis of clinical data regarding the state of the art and the post-market surveillance plan referred to in Article 84.

Key principle:

1, 2, 3

No. 4

Issue and current requirement:

Eudamed content

Qualification of bureaucratic issue:

MDR and IVDR requirement

Repeated depiction of EUDAMED

content (e.g. EMDN codes) in technical documentation and certificates

Explanation:

The administration of multiple copies of product content (e.g. EMDN codes) in technical documentation and certificates is coupled to a tremendous effort, especially for large product portfolios. With EC-intended annually routine rework of EMDN database a good example of artificial workload on a mass of documents and risk for invalid certificates is set up by the EC.

Rationale:

Since the content to be delivered for each product to the Eudamed database for administrative reasons is to be released either by the Notified Body or in responsiveness of the legal manufacturer anyway. Thus, the ultimate lifecycle of these data shall be exerted in the database – fully accessible for all instances and transparent to the world. It is not reasonable to depict such data again on several documentation instances, unless BASIC UDI-DI and UDI-DI is annotated. The current situation leads to unnecessary burden by reissuance of documents or certificates with direct impact on product availability and human resources.

Resolution:

Proposed instrument / legal basis for resolution:

Identify the content in the EUDAMED database, that is a necessary copy of product data (e.g. warnings) and those data, that are sufficient to be available in the database solely, since they are released there anyway for certification by the relevant parties. Restrict duplication of data outside EUDAMED on the necessary content.

Description:

Ideally, the attributes depicted in EUDAMED have a specific reason (maybe risk mgmt driven as for storage temperatures etc.) to be depicted outside of the data set in the technical documentation. In fact the EUDAMED data are extended certification data.

Key principle:

No. 5

Issue and current requirement:

SSP for IVD

Qualification of bureaucratic issue:

IVDR Requirement

Explanation:

SSP is to be made available over EUDAMED especially with the purpose of informing lay users of assay performance and safety aspects.

For professional use assays the patient has no connection to the assay and therefore, no ability to access the SSP. Professional users have a much deeper understanding of assay performance, limitation and risks. In addition, they often have contact to the manufacturers expert not available to lay persons.

Potential additional information gained from the SSP as compared to IFU and other product information material is negligible to non-existent.

Rationale:

This legal requirement is an example of copy-and-paste from the MDR to the IVDR. The SSCP was intended for implantable MDs that remain in the body for years of decades, potentially posing ongoing risks to patient safety. A test that is used outside the human body, providing a one-time result is not comparable and should be handled differently.

Equating these very different product types in terms of risk communication is disproportionate and misaligned with the intended purpose of the SSCP.

Resolution:

Proposed instrument / legal basis for resolution:

Option 1: Removal of IVDR article 29 and annex VI (A) 2.11

Option 2: Amendment to article 29 (1) IVDR as follows:

1. For class C and D lay use devices, except for devices for performance studies, the manufacturer shall draw up a summary of safety and performance.

Description:

Key principle:

No. 6

Issue and current requirement:

Classification of class B devices IVDR | Self-assessment

Qualification of bureaucratic issue:

IVDR requirement

Explanation:

Removal of surveillance audits for class B devices with the exception of review of PMS material to reduce the burden on the system and eliminate bureaucratic reports with no patient benefit.

Rationale:

For the IVDR the policy choice was made to enormously increase the devices under the requirement for notified body conformity assessment where these devices were subject to self-assessment under the IVDD This policy decision has not been motivated by safety or performance issues with IVDs under the IVDD and does not serve a purpose of increasing patient safety or test performance. As a result, the continued conformity assessment system under the IVDR is congested with a large amount of low risk (class B) devices that used to be subject to self-assessment.

For these devices the notified body capacity under the IVDR is scarce and of which the added value of notified body continued conformity assessment identical to C and D is questionable. This creates an enormous extra cost to the healthcare system that is not justified by any benefits in terms of increased performance or safety of tests.

The replacement of surveillance reviews for class B with reduced technical file reviews focused only on PMS data would underline the different inherent risks to class C/D devices.

Furthermore, current Class A devices are being monitored by national competent authorities.

The Impact Assessment predicted a significant increase in costs for manufacturers (which indeed took place) but justified these based on “enhanced robustness of the classification system, as well as international harmonization”. So far the advantages that underlay this policy choice have not materialized and industry does not expect them to materialize without recalibration of the IVDR’s certification process.

Resolution:

Proposed instrument / legal basis for resolution:

Add to Article 49 the following point: *for class B in vitro diagnostic devices the involvement of the notified body in surveillance shall be limited to quality management system audits and review of post-market surveillance data. No*

surveillance audits involving product sampling or technical documentation file checks shall be required for class B devices.

Add to Article 78 (1): *For Class B devices, the post-market surveillance system shall be subject to review by the notified body solely concerning post-market surveillance data, without the requirement for routine surveillance audits.*

Amend Annex IX, Section 3.3: *3.3. Notified bodies shall periodically, at least once every 12 months, carry out appropriate audits and assessments to ensure that the manufacturer applies the approved quality management system and the post-market surveillance plan. For Class B devices, the notified body's assessment shall be limited to the review of post-market surveillance data provided by the manufacturer, without conducting routine surveillance audits.*

Amend Annex IX, Section 3.5: *3.5. In the case of Class C devices, the surveillance assessment shall include an assessment of the technical documentation as specified in Section 4 for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the third paragraph of Section 2.3. For Class B devices, the surveillance assessment shall be limited to the review of post-market surveillance data, without the requirement for routine surveillance audits or additional assessments of technical documentation.*

Amend Annex VII Section 4.10: *The notified body shall have documented procedures:... (b) for screening relevant sources of scientific and clinical data and post-market information relating to the scope of their designation. For Class B devices, such information shall be taken into account solely in the review of post-market surveillance data provided by the manufacturer, without conducting routine surveillance audits.*

Instead, the formal legal procedure to determine the regulatory status of products should be used, as it requires structured presentation and evaluation of arguments. We advocate for the consistent application of existing legal instruments, particularly Article 4 MDR and Article 3 IVDR for decisions on the regulatory status of a product and Article 51

(3) MDR and Article 47

(3) IVDR for decisions on the classification of a device.

Description:

Key principle:

No. 8

Issue and current requirement:

Sampling of technical documentation of class IIa and IIb products (Art. 52, 4-6, Ann. IX, Ch I, Section 2, 3)

Qualification of bureaucratic issue:

MDR requirement

Disproportionate and repeated sampling of technical documentation

Explanation:

Article 52, paragraphs 4-6 MDR, and Annex IX, Chapter I, No. 3, specify the assessment of technical documentation on the basis of representative samples.

The sampling shall take into account MDCG-Guidances, technological novelty, similarities in design, technology, manufacturing and sterilization processes, the intended purpose and the results of any relevant previous assessments, e.g. with regard to physical, chemical, biological or clinical properties. (Annex IX Section 2.3)

Before issuing the certificate, the notified body must examine the technical documentation of at least one representative product per category (for Class IIa) or per generic product group (for Class IIb), Art. 52 (4) and (6) MDR. Specifically, this means that for each category covered by the manufacturer's application (Class IIa) or for each generic product group (Class IIb), a representative product must be randomly selected, and the corresponding technical documentation must be fully evaluated.

These evaluations are required before the QMS certificate is issued and are included in the final assessment in accordance with MDR Annex VII Section 4.7.

In Annex IX Chapter 3.5 it is further specified that the surveillance audit shall also include an assessment of the technical documentation on the basis of the represtantive samples and the rationale in Section 2.3.

The scope of the random samples is further specified in the guideline MDCG 2019-13 (Rev1, Dec 2024).

This defines the criteria on a flat-rate basis using minimum quantities specified as percentages based on generic product groups (Class IIb) or product categories (Class IIa). It is also specified, that due to its inclusion in the surveillance audit, it is the opinion of the MDCG that one random sample is required every year.

Issues:

While the generic device group is defined in Article 2 (7), there is no definition in the MDR for a category of products. The MDCG has determined to use the 4th level of EMDN Codes (3rd level for IVDR) and the MDA/MDN Codes respectively.

This approach is not practical in many cases the 4th level of EMDN-Codes is partially stratified to an extent where technologically nearly identical products with a similar intended purpose can have different codes, triggering additional, duplicative TD-Reviews.

The MDCG additionally only takes one certification period into account. In the event of recertification, some notified bodies interpret this to mean that the sampling plan is reset. So a TD that was already reviewed in last year's surveillance audit, and has not been changed, can be subject to review again.

In the case of SME's or other companies with a small product portfolio, TD's that already have been sampled are often reviewed again, even if there have been little to no changes to the product or the documentation.

This does not lead to patient safety but causes administrative burden, blocks capacities for other important topics and leads to significant costs, especially for SMEs

Rationale:

In cases where there is little to no change in the Technical Documentation reexamining the same Technical Documentation provides no substantiative value and places an undue burden on the manufacturer. Sampling activities should follow the rationale of proportionality.

The principle of proportionality is central to the decision on sampling – not only how, but whether and how deeply testing is carried out. MDCG 2019-13 equates the depth of assessment for a technical documentation of a Class IIa / IIb device with the assessment of a class III device. Especially in the case of repeated review of the same file this is directly opposed to the principles of risk-based assessment.

Resolution:

Proposed instrument / legal basis for resolution:

Amend Annex IX, Chapter I, No. 3.5 to exclude Class IIa devices from sampling obligation during surveillance audits. (Delete ~~"class IIa and"~~).

Amend Annex IX, Chapter I, No. 3.5 to exempt WET from sampling obligation during surveillance audits. (add: *Well Established Technologies shall be exempt from this obligation*)

Amend Annex IX 3.5 to make clear that the surveillance audit only includes an assessment of the technical documentation where appropriate and necessary. And that prior assessment activities in regard to technical documentations need to be taken into account when determining if another review is necessary.

Amend Annex IX to make clear that the same technical documentation does assessed twice if no significant change has occurred. This can be achieved by adding language stating that prior (years / certification cycles) assessment of comparable technical documentation is to be taken into account.

TechDoc Review should be focused on clinical not the complete TechDoc. Change Annex IX 3.5 to only reference 4.4- 4.8 instead of complete section 4.

Amend Article 2 (7) and include a definition for category of products. Amend Article 52 to make clear, that the manufacturer and the notified body jointly come to an individual determination on groupings, determined among other factors by the MDA / MDN scopes.

Description:

Class IIa products should only be sampled within the initial review. Additional sampling during surveillance audits is unnecessary. Only in the event of changes, anomalies, vigilance data or trends, should further TDs be reviewed.

For WET, a reduced or waived testing rate should be possible.

There is no reason why a yearly review of a technical documentation is necessary, if no issues arise from vigilance/changes/anomalies etc.

Repeated checks of documents that have already been assessed should not take place without cause. A yearly review of the same or comparable technical documentations is not proportionate.

Change back the focus of the review of technical documentation on clinical. Sections 4.4-4.8, as specified in the first published version of the legal act, and not on the complete TD as introduced with Corrigendum, OJ L 117, 3.5.2019, p. 9 (2017/745)

The generic product group should no longer be defined via the 4th EMDN level (Class IIb). Instead, it should be determined individually and by mutual agreement with the notified body at the start of certification in accordance with Art. 2 No. 7 MDR. Medical devices are too complex in their variety to be captured in a generic manner

Key principle:

No. 9

Issue and current requirement:

Adapt to Modern Formats of Documentation

Qualification of bureaucratic issue:

MDR/IVDR Requirement

Divergent Notified Body practice

Explanation:

Documentation historically is understood to be made up by structured content (e.g. pages in a PDF)

However, in more recent years, technology has allowed for more modular approaches toward documentation.

For example, Technical Documentation can be viewed as a collection of content/data managed in own lifecycles according QMS processes.

These pieces of content are repeated in many different sections within technical documentation (e.g. intended use) for legibility. This setting is highly prone to errors as information ´s lifecycle elicits delays in revision of documents depending on its individual information compilation with simultaneously review.

In a more modular or data-driven approach, the intended use and other parts of the documentation could be sent as separate modular datapoints. The Notified Body could then generate a complete sequential Technical Documentation from these datapoints. This way of submitting information for technical documentation has multiple advantages over a classical approach.

The same is true for various other kinds of documentation (Clinical, Biocomp etc.).

At the moment Notified Bodies often do not accept data-driven submissions. In part, because they see the legal obligation, for a document to be generated in a structured manner, to be eligible for submission

Rationale:

The current situation is replicating data/information within documentation according to the specific needs of the individual reader. More advanced methods of structuring information in documents are available and should be permitted to be used.

It is possible to manage and consent to the release of legally binding information via the data itself, as shown by EUDAMED content.

Resolution:

Proposed instrument / legal basis for resolution:

Harmonize the Understanding of Documentation within the MDR and IVDR to make clear that e.g. modular or data driven submission is legally permitted.

This would for example with regard to technical documentation. Enable a compilation in a modular, data-driven resp. digital format according manufacturers processes (audited and certified) towards Notified Bodies instead of compilation of pdf documents.

Description:

Make clear in what cases Documentation can refer to (signed, validated, approved, released) information and not a certain structure of information. Allow for the possibility of data-driven submissions.

Key principle: 2