Statement of the TÜV Association (16/12/2024) on the

Joint paper of Croatia, Finland, France, Germany, Ireland, Luxembourg, Romania, Malta and Slovenia on necessary reforms in MDR and IVDR: priorities / main points

On 03 December 2024, the EPSCO council discussed a joint paper of Croatia, Finland, France, Germany, Ireland, Luxembourg, Romania, Malta and Slovenia on necessary reforms in MDR and IVDR[1]. The paper identified five priorities / main points for the revision of the two regulations.

The TÜV Association would hereby like to comment these five priorities / main points:

1) Reduction of administrative obligations of stakeholders

We support the goal of reducing unnecessary bureaucracy. However, the aim of standardising and reducing requirements to the necessary level should not be limited to conformity assessment procedures, but should start with the designation procedures and the requirements for notified bodies.

In the interests of patient safety, we consider it very important that the current certification cycle is maintained and that the intensity of monitoring is not reduced. To reduce bureaucracy and costs for manufacturers, it would be possible not to reissue certificates every five years, but to remain them valid after re-certification and to extend validity without issuing a new certificate.

We would like to emphasise that re-certification is not a full repetition of the initial assessment. The strong focus of re-certification is already today on new and changed aspects, safety aspects linked to post-market surveillance, vigilance and market surveillance and it is proportionate to the class of the risk. In addition, we would like to point out that product certificates are mostly high-risk products. Changes in this area should be well thought out and the existing and emerging risks should be considered.

Nonetheless, the scope and content of re-certification require a critical review. Not all MDR requirements need to be reviewed every five years. It should be possible to take the results of previous monitoring measures into account during re-certification. A precise definition is required – this could form part of an MDCG document, for example.

2) Centralisation of system management functions to the EMA

We support the proposal to pool competences and tasks in a centralised and qualified European body or entity. Different interpretations of requirements by authorities, contradictions in MDCG documents and

[1] https://data.consilium.europa.eu/doc/document/ST-15380-2024-INIT/en/pdf

long processing times are a central problem in the implementation of the MDR and IVDR.

We would welcome a strengthening of the role of the MDCG and the administrative secretariat. In particular, this requires better staffing. Such a measure would already be possible under the current legal framework. In particular, mechanisms should be created to avoid and correct different interpretations of requirements for notified bodies by authorities. The aim should be to implement all requirements as uniformly as possible across Europe in order to avoid distortions of competition and create a level playing field.

We do not consider the involvement of the EMA in the procedure to be appropriate. The EMA's focus is on the area of medicinal products. The EMA has little experience in the area of medical devices and no experience in the area of designation procedures. One of the aims of revising the MDR and IVDR should be to reduce unnecessary requirements and simplify the system. This hardly seems possible due to the creation of new official structures and new interfaces. In the worst-case scenario, a corresponding implementation would take a long time and increase the costs of market access for medical devices.

3) Foreseeable and balanced certification procedures

We support the goal of appropriate, transparent and predictable timelines for certification. In all considerations, it must not be forgotten that the reasons for lengthier conformity assessment procedures can be diverse:

- Almost all manufacturers are currently undergoing initial certification and the processing time for this is longer as manufacturers have more non-conformities to address.
- Hardly any of the applications for certification submitted to a Notified Body are complete; they do not include all of the legally required documentation/evidence.[2] While some issues (like adding a signature) are relatively easy to resolve, there may be issues that can only be resolved over a longer period of time (such as missing or incomplete clinical data).
- The quality of manufacturers' implementation of the MDR requirements varies significantly.
- Before the certification can be completed, the manufacturer must first implement the necessary corrective measures.
- Complexity of the manufacturer's structures (such as the number of subsidiaries worldwide) and the number of products (from one or well over one thousand).
- New or amended requirements by authorities (in particular, MDCG documents) that must also be taken into account in ongoing procedures.
- The Notified Bodies have limited reserves of staff, meaning that manufacturers may have to wait for their corrective measures to be reviewed.

[2] Cf. Team NB - Medical Device Survey 2023, p. 23 (www.team-nb.org/wp-content/uploads/2024/05/Survey-2023-20240513.pdf)

It should also not be overlooked that much has developed and improved in recent years. In particular, the issue of insufficient capacities of notified bodies has been resolved, which will have a positive impact on the average duration of certification procedures in the future.

Certification procedures for medical devices are characterised by very different levels of complexity. We therefore consider the mere definition of a time frame for the entire certification process to be unsuitable as a sole measure. More detailed and far-reaching specifications are required. For example, the amount of time required to review individual aspects should also be specified.[3]

When stop-the-clock-options are introduced, certain stipulations are required with regard to patient safety: If the specified times are not adhered to despite these stop-the-clock-options, this must not lead to certification or a certification under conditions as a result of the deadline expiring. In terms of patient safety, but also in terms of liability consequences for the notified bodies, this would not be justifiable.

4) Taking into account specific needs for medical devices intended for specific patient populations

When discussing the reduction of administrative burdens, certification should not be seen as an administrative burden. Certification serves to check whether a manufacturer or product fulfils the regulatory requirements. If there is an overload here, it is not the fault of the monitoring mechanism, but rather the design and scope of the legal requirements. Administrative burdens arise largely from the legal requirements and expectations of the authorities. Every manufacturer must fulfil the relevant legal requirements, regardless of whether certification is necessary or not. Better regulation ultimately means faster and safer certification, and certification ultimately serves to protect patients. As some manufacturers are obviously unable to fulfil the current legal requirements, we expressly welcome the proposal to better empower manufacturers.

We see the need for exemptions and supporting measures for individual products and product groups. In this context, with the document MDCG 2024-10 "Clinical evaluation of orphan medical devices"[4], significant step was made. Clear exemptions have now stipulated and a very good framework for the market access of niche products (orphan devices) was created. Such measures are also conceivable for other products or product groups.

5) Assuring a special pathway for innovations

There are already today extensive opportunities to bring innovations to the market under the existing scopes and certifications without the need for reassessment or re-certification. Nevertheless, we

[3] Approaches to this can be found, for example, in the Code of Conduct for Notified Bodies by Team-NB.
[4] https://health.ec.europa.eu/document/download/daa1fc59-9d2c-4e82-878e-d6fdf12ecd1a_en?filename=mdcg_2024-10_en.pdf

support the proposal for a special and adapted pathway for novel and innovative devices and of specific pathways for technologies which are considered breakthrough or for those which address unmet clinical needs. The expert panels can play a central role here.

Manufacturers must draw on significantly more resources to make their products MDR or IVDR-compliant than compared to the directives. This is due to far more stringent requirements in the clinical field, for instance. Given their innovative nature and/or the small market, this increased complexity has a disproportionately strong negative impact on innovative and novel products. There is an urgent need for clear, legally permissible exemptions for these products. One major obstacle in the conformity assessment of these products is usually that insufficient clinical data is available, at least compared to many of the other products on the market. The MDR does not provide any clear criteria for exemptions here. At the same time, the assessment of technical safety does not pose an obstacle – not even for innovative and novel products.

With the document MDCG 2024-10 "Clinical evaluation of orphan medical devices"[5], clear exemptions have now been stipulated and a very good framework for the market access of niche products (orphan devices) was created. With regard to novel and innovative products the development of specifications based on MDCG 2024-10 would be welcomed here. However, to speed up the market access of products, manufacturers should be required to carry out the necessary consultations before the Notified Body begins its conformity assessment.

Such a simplified procedure could take a similar form to a "special track" procedure: The assessment of clinical data could be carried out by a European institution or a central European body (such as the expert panels). Their decision would then be binding for Notified Bodies. In this process, the period within which a re-evaluation of the clinical data must take place and at what point a product or application is no longer considered "innovative" must also be determined.

In addition, specific pathways for technologies which are considered breakthrough or for those which address unmet clinical needs are another possibility.

The model of a regulatory sandbox is not yet clear to the notified bodies, especially in relation to the conduct of clinical trials.

For all of these products, the classification of when a product is novel, innovative, a breakthrough technology or a technology that address an unmet clinical need, clear criteria that are based on legal requirements and/or decisions by authorities prior to the involvement of a Notified Body in the conformity assessment are needed. In particular, there is a need for differentiation from the pure evolution of a product.

[5] https://health.ec.europa.eu/document/download/daa1fc59-9d2c-4e82-878e-d6fdf12ecd1a_en?filename=mdcg_2024-10_en.pdf

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