Position on the Commission public consultation

Draft Implementing Regulation laying down uniform requirements for Notified Bodies designated under MDR/IVDR

General remarks

The TÜV Association and IG-NB welcome the European Commission's efforts to harmonise conformity assessment requirements of Notified Bodies operating under Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR). However, these efforts must not result in requirements being imposed on Notified Bodies that cannot be fulfilled or that create more bureaucracy. Efforts to accelerate conformity assessment procedures must not come at the expense of product and patient safety.

There is a risk that these requirements will not result in the envisaged outcome by the EU Commission but will result in inflexibility within conformity assessment procedures and therefore hinder the proposed goal of faster market access. This is especially applicable to SMEs. Further, the proposal does not take into consideration the risk classification and the assessment of complex, high risk medical devices or where a manufacturer may submit a large portfolio of devices.

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

Our suggestions

Article 1 – Quotations

Article 1(1)b: The draft proposes that Notified Bodies shall *determine if the manufacturer is a micro, small and medium-sized enterprise as defined in Commission Recommendation 2003/361/EC, namely the number of employees and the annual turnover*. Anyhow, the SME status verification and its continuous monitoring based on the criteria named above require resources and expertise to review financial statements. This would create extra work, slow down application processing, and increase costs. Self-declarations from manufacturers are not validated and are therefore unreliable. We suggests that SME status should be verified and recorded in EUDAMED during user registration. This would allow a transparent verification mechanism of a manufacturer (whether SME or not) for all stakeholders, including Notified Bodies.
Alternatively, the allocation as an SME may remain voluntary, as some organizations may choose to utilize this status, but some may not require it and therefore opt to avoid the administrative aspects of

this in the interest of time. Allowing device certification only for companies who disclose corporate details not related to the device itself constitutes an unnecessary hindrance.

Article 1(3)(c): Notified Bodies operate on a global level delivering conformity assessment activities across the world dealing with local requirements. We cannot see any added benefit and or value in providing an estimation of travel and accommodation costs at quotation. Travel costs will vary based on quoted and actual values depending on when actually booked. Based on travel policies, Notified Bodies ensure that cost-efficient choices are made. We see no value in this inclusion and proposes the removal of Article 1(3)(c) from the Draft Implementing Regulation.

Article 2 - Timelines

The proposed timelines of conformity assessment activities are too ambitious and risk compromising the quality of assessments, increasing costs, refusals of applications and as consequence time to market for manufacturers.

The requirement that the Notified Body shall in any case ensure that conformity assessment activities are completed according to maximum timelines significantly restricts the flexibility that may be needed in conformity assessment procedures. Until now, manufacturers could agree with their Notified Body to submit the documentation in stages and apply a rolling-review approach. However, with the newly proposed strict maximum deadlines for each individual step of the certification process, this pragmatic mode of operation will no longer be feasible. To meet these deadlines, Notified Bodies will only be able to accept fully complete documentation to start the assessment. Any incomplete submission – even if most documents were made available and an assessment could theoretically begin – would have to be refused.

The definition of fixed maximum durations for individual procedural steps does not sufficiently reflect the integrated nature of the conformity assessment process, in which the assessment of the Technical Documentation and the auditing of the Quality Management System are inherently interdependent. Factors that may legitimately extend the overall duration of the process are in practice the identification of previously unknown facts, scheduling constraints on the side of either the manufacturer or the Notified Body, as well as incomplete, inconsistent or missing information provided by the manufacturer.

As a result, a certification procedure might fail shortly and need to be terminated before completion simply due to the strict deadline regime. Manufacturers would then be forced to initiate new certification procedures, leading to higher costs compared to the current situation and time to market.

When determining processing times, it must also be considered that Notified Bodies are legally required to conduct assessments with the highest degree of professional integrity and free from any pressure.

Unbalanced or overly accelerated timelines may compromise safety-related decision-making. To compensate, Notified Bodies might need to allocate additional qualified experts to individual conformity assessment procedures to meet legal obligations, which would further increase certification costs.

Proposed amendments:

As regards the specific timelines set, in particular the 120-days-deadline for quality management system auditing and the 90-days product verification-deadline are far too short to be able to review all legal requirements adequately. For technical documentation assessments to be adequately finalized as part of the quality management system certification route, a 180-days-deadline for all technical documentation assessments or a 120-days-deadline for a single technical documentation assessment is much more realistic. It allows sufficient time to evaluate the large number of products within the range of quality management system scope and to involve the necessary internal and, in particular, external experts. For product verification to be adequately finalized, a 120-days-deadline is much more realistic.

In addition, opening clauses could take into account the complexity of individual products, of individual conformity assessment procedures, or of situations in which a manufacturer holds several certificates by a Notified Body that have the same validity date. The European Commission should introduce opening clauses in Article 2 that allow for longer procedures (initial certifications and substantial changes) if both the manufacturer and the Notified Body agree. This would not have a negative impact on any KPIs established by this implementing regulation.

Alternatively, the onetime amendment of 30 days in duly substantiated cases - as it is introduced for the Clinical evaluation consultation under the Draft MDR change Annex IX, 5.2(d) – could be considered as an additional measure to keep up with the assessment with the highest degree of professional integrity and the requisite technical and scientific competence in the specific field at least for the devices of Class IIb and III.

The 15-days deadline for the final decision and certification is equally restrictive due to the limited number of qualified staff. In practice a 25 days-deadline is more practical, especially when the final review and certification are combined.

Article 3 – Interruption of work on conformity assessments

Generally speaking, the introduction of a maximum number of work interruptions ("clock-stops") will result in limited exchange between the manufacturer and the Notified Body. Establishing such a measure would lead to the consequence that a conformity assessment procedure is stopped, and negatively closed, if the manufacturer is unable to clarify open questions or fails to submit the required full documentation within the given number of requests from the Notified Body. To restart the assessment the manufacturer has to re-apply for the assessment procedure, leading to higher costs for manufacturers compared to today. According to the practical experience this is specifically applicable to SMEs.

More frequent requests/enquiries by Notified Bodies are in the manufacturer's interest and should therefore be made possible. Similar to the proposal for Article 2, an opening clause should be introduced in Article 3 to allow for further clock-stop options (in every step of the conformity assessment procedure) if both the manufacturer and the Notified Body agree. So far, this possibility only exists with regard to the duration of the clock-stop options. The introduction of further clock-stops will significantly increase the

number of positive assessment results as the manufacturer would be given more opportunities to provide the necessary evidence of product and patient safety.

The proposal does not allow Notified Bodies to interrupt their work in the process of the final decision and certification. In order to prevent conformity assessment procedures to fail shortly before their completion due to minor issues (e.g. still missing information from the manufacturer), an additional clock-stop should be introduced in point 1 for the phase of the final decision and certification.

Deadlines for manufacturers to submit additional documentation as a subsequent submission should also be regulated, as otherwise – especially considering the tight timelines defined in Art. 2 – Notified Bodies will have to permanently reserve resources for re-evaluation.

In the draft MDR change Article 35 is supplemented by an appeal procedure. Such a procedure would require an additional clock-stop, as otherwise this time would be counted towards the notified body's assessment time.

Article 4 - Monitoring of the duration and costs

The proposed requirement for Notified Bodies to establish a system to monitor the duration of conformity assessment activities and their costs appears to be questionable. Although manufacturers can get an impression of the potential costs of certifications, the reporting system would only generate highly aggregated data (as, for instance, medical devices with different risk classes are listed together) with a limited significance. The same or a better information content can be achieved by obtaining quotes.

Conformity assessment procedures are highly individual, both in terms of duration and cost, and depend on a variety of factors. This includes the complexity of product design and implementation, the chosen conformity assessment route, the maturity and completeness of the manufacturer's documentation, the number of production facilities and critical suppliers to be covered, the deployed qualified personnel of the Notified Body, the salary structures in the respective country, etc. Thus, even for identical or similar products, the duration of the conformity assessment process may vary, even in the best-case scenario. In addition, the minimum and maximum costs and times also may result from different depths of assessment between European Notified Bodies. Without a uniform definition of the depth of assessment of audits and, above all, technical documentations, it is not possible to meaningfully compare costs and times.

The foreseen publication of the annual report on timelines and costs of conformity assessment activities on the website is likely to lead to price pressure on Notified Bodies. This is 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.*"

In addition, this contrasts with the requirement, that Notified Bodies shall *"have documented procedures in relation to advertising of their conformity assessment services. Those procedures shall ensure that advertising or promotional activities* ***in no way imply or are capable of leading to an inference that their conformity assessment will offer manufacturers earlier market access or be quicker, easier or less stringent than that of other Notified Bodies****"* (Annex VII (4.2) MDR and IVDR).

The practical consequence of such a reporting system would be that the high quality of certification services and in consequence patient safety is put at risk. In addition, Notified Bodies would face (unnecessary) additional bureaucratic burdens that, in turn, could make procedures more expensive.

If a comparison of cost structures and pricing is politically intended, it should be carried out under the umbrella of the Medical Device Coordination Group and within the framework of joint assessments. This would avoid the impression that the legislator aims to exert price pressure on the Notified Bodies.

Article 5 – Launch of re-certification

Tracking relevant expiration deadlines of certificates is an integral part of the manufacturer's compliance system. Given the vast number of requirements that medical device manufacturers have to fulfil, it can be reasonably assumed that they are capable of tracking relevant deadlines on their own. There is no need to require Notified Bodies to inform all of their manufacturers accordingly, as this would only create an unnecessary additional bureaucratic burden and increase the costs of a certification.

Article 6 – Re-certification for product certificates and Article 7 – Re-certification for quality management system certificates

The proposed requirement for Notified Bodies to review the documentation from the manufacturer within a 60-days-deadline (Article 6 Point 3 and Article 7 Point 6 (3)) cannot be realized in practice due to several constraints.

First, the requirement that the deadline begins with the manufacturer's application contradicts Article 1 of this regulation. A mere application cannot be used as a basis for assessment, as the manufacturer has at this point not yet provided the Notified Body with all relevant information. The corresponding 60-day period may only begin once all the information necessary for recertification have been provided by the manufacturer, and the offer has been made by the Notified Body and accepted by the manufacturer. Otherwise, certain recertification procedures would have to be stopped at the deadline due to missing documentation. New procedures would have to be initiated, with higher costs for manufacturers compared to today.

Second, the 60-days-deadline is too short in practice. The Notified Bodies have limited resources, which they must distribute as fairly as possible among all their clients. To do so, they must also be given sufficient flexibility. A deadline of 100 days would be more realistic.

The Draft Implementing Regulation does not specify timelines for manufacturer submissions for recertification. This should be defined to provide predictability to the process and avoid delayed

submissions close to the expiry date of the certificate. Notified Bodies typically need at least 9 months to plan and conduct re-certification.

Article 8 – Decision on re-certification

The proposal does not allow Notified Bodies to interrupt their work in the process of the final decision and certification. In order to prevent conformity assessment procedures to fail shortly before their completion due to minor issues (e.g. still missing information from the manufacturer), an additional clock-stop should be introduced for the phase of the final decision and re-certification. The 15-days-deadline for the final decision and re-certification is equally restrictive due to the limited number of qualified staff. In practice, a 30-days-deadline - taking into account that EUDMED must be updated afterwards - is more practical, especially when the final review and decision-making step is combined.

Article 9 – Transitional provisions

Notified Bodies need sufficient time to implement the new requirements in their internal procedures, adapt their quotations, adjust their audit and certification planning, train their staff, implement respective tools and infrastructure, etc., without delaying ongoing procedures. The proposed transition periods are too short and should be replaced by more realistic ones (an additional 12 months for every timeline). A timeline for the changes to the quotation process is missing and should be added (at least 6 months).

Article 10 – Entry into force and application

Experience gained from previous extensions of transitional timelines indicates that manufacturers may tend to approach their Notified Body only toward the end of the applicable deadlines.

The Implementing Act shall clarify that these rules only apply to new applications for conformity assessment procedures, i.e. if a manufacturer has already applied to a Notified Body, a withdrawal of that application and re-application to the same or other Notified Body shall not entitle the application to be covered under the new timeline rules.

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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.

IG-NB (Interessengemeinschaft der Benannten Stellen für Medizinprodukte in Deutschland) represents the interest of all German notified bodies for medical devices. The aim of the IG-NB is to develop positions and to coordinate and bundle the interests of the German notified bodies in order to better represent them vis-à-vis industry and authorities. The IG-NB is managed by the TÜV Association.

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