

## Considerations on the current process of harmonisation of standards under the IVD Regulation and Medical Devices Regulation

MedTech Europe's position paper, June 2021

MedTech Europe welcomes the approval of the Standardisation Request [M/575 COMMISSION IMPLEMENTING DECISION of 14.4.2021](#) for the *In Vitro* Diagnostic Medical Devices Regulation (“IVDR”) and Medical Devices Regulation (“MDR”). The European Commission has worked closely with stakeholders and the standardisation organisations to ensure this achievement ahead of the MDR Date of Application. This paves the way for harmonised standards for medical devices and *in vitro* diagnostic medical devices (“IVDs”) to be cited in the EU Official Journal. To ensure that this publication is followed by a smooth and speedy process of harmonisation, MedTech Europe has put together a set of recommendations to be addressed to, and discussed with, the relevant parties, especially the European Commission.

### Introduction

MedTech Europe is in favor of the publication of harmonised standards needed to support implementation of the IVDR/MDR. Although the application of harmonised standards to demonstrate compliance against the general safety and performance requirements or other legal aspects is voluntary, we recognize them as being a key pillar of New Legislative Framework legislation, including the IVDR/MDR. Standards have been widely used for years as the recognised route to compliance under the medical devices' directives. MedTech Europe highlights the global nature of the industry it represents and the need to align technical requirements to those generally agreed at international level.

The lack of harmonised standards for IVDR/MDR in many horizontal and product-specific areas poses challenges for manufacturers, e.g., for conformity assessment, compliance with post-market requirements, when implementing significant changes to devices or quality management systems, etc. Therefore, harmonisation of standards is needed as soon as possible.

Particular requirements contained in Annex III of the Standardisation Request may be interpreted by the relevant harmonised standards (“HAS”) consultant(s) in such a way that they reject critical standards from being harmonised. In the best interest of both parties, HAS consultants and the Technical Committees of the European Standardisation Organisations, these requirements need to be clarified to create a fair and level playing field for technical experts preparing the Annexes Z as well as for HAS consultants. **MedTech Europe calls on the European Commission swiftly to ensure a consistent approach by HAS consultants allowing new and existing standards to be positively assessed to the requirements of the**

**Standardisation Request, in particular for horizontal standards as these are the most likely category of standard to fail under certain Annex III requirements of the Standardisation Request.**

**The following aspects of Annex III need to be urgently addressed by the European Commission:**

- Some 'horizontal' standards (e.g., ISO 14155, 14971, etc.) cannot have 'technical' content in the same manner as a product-specific standard (i.e., like those in the IEC 60601 series) since they outline how to implement a process or fulfill horizontal requirements, but not how to test a product. Additional clear interpretation of Annex III should be provided urgently by the European Commission which will support the harmonisation for these so-called "horizontal" or process standards. MedTech Europe asks for clarifications to be laid down in form of a guidance for HAS consultants and CEN/CENELEC Technical Committees.

For example, we note the recent rejection of ISO 14971 Annex Z. Given the importance of horizontal standards – as they affect ALL medical devices and should be harmonised against the IVDR/MDR as a matter of priority – a solution needs to be found to bring these standards into the European legislation.

- The terminology used in an international standard does not match 100% with that of the IVDR/MDR, since it considers many jurisdictions and often the standard originated earlier than the Regulations. Moreover, many standards define specific terms, which are urgently needed to unambiguously define its requirements, but which are not defined in the IVDR/MDR. If the HAS consultant decides that a term is a "legally relevant term" then its definition by a standard is forbidden and will hinder the harmonisation of that standard. We consider the definition of terms being crucial and which should not create obstacles to harmonisation. We ask that the European Commission either provides the standards experts with a list of "legally relevant terms", or, preferably, clarify that the Annexes Z should include a statement to the effect that the definitions set out in the IVDR/MDR prevail for the purpose of using the harmonised standard for the compliance to the European requirements. This will set out how specific terms should be understood for the purpose of IVDR/MDR without triggering the need to change the text of the international standard.
- Many standards reproduce requirements contained in the IVDR/MDR as this is necessary to align the European requirements to those applicable in other jurisdictions. It is vital that this continues to be the case as it enables Europe to continue exporting its rules – and therefore exporting its products – globally. The Annex III implies that no IVDR/MDR requirements can be reproduced in the text of the international standards. The European Commission should clarify that this means that the Annexes Z should not harmonise the sections of the standard where the text is the same, i.e., not more stringent. Reproducing the IVDR/MDR requirements into international standards should be celebrated and supported by the European Commission.
- Standards which normatively refer to other standards – a well acknowledged practice in standardisation – are especially at risk of not being harmonised. Surprisingly, Annex III first defines strict requirements for

such normative references before forbidding their use in the last sentence of the same paragraph. Clarification from the European Commission is needed to ensure that standards may normatively refer to other standards under the harmonisation framework, but that these specific requirements coming from normative references i.e., other standards, shall not be used to confer a presumption of conformity in the Annexes Z.

- When a standard is harmonised, the manufacturer needs time to transition to the new requirements. This implies a re-organisation of the manufacturers' processes which can take up to 3 years in the case of complex, horizontal standards. Therefore, a transition time to allow for the changes to be implemented is highly recommended. Moreover, a detailed work plan or a list in which order the standards are being prepared from the standardisation organisations will give manufacturers a better perspective on the priorities.
- We strongly urge the European Commission to liaise with the CEN-CENELEC Management Committee on creating a public database where the information is stored in all transparency, including the reports from the HAS consultants, the status of each standard and the working plan.
- In addition, we believe a fair mechanism to contest the decision of the HAS consultant should be available to all stakeholders. To promote transparency, the decisions of the HAS consultants should be made publicly available.

**MedTech Europe supports the approval of the Standardisation Request. At the same time, we seek further discussion with the European Commission to find a pragmatic approach for the obstacles on the way to harmonisation of standards for the medical devices and IVD sectors. Sectors, which, by their very nature – covering around 500.000 types of products utilising an incredibly diverse range of technologies – deserve a specific set of rules which might be different from those needed for more homogeneous technological sectors.**

## About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, visit [www.medtecheurope.org](http://www.medtecheurope.org).

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