

MedTech Europe position on the proposed draft Standardisation Request for *In-vitro* Diagnostic Medical Devices (IVD) Regulation (2017/746/EU) and Medical Devices (MD) Regulation (2017/745/EU)

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MedTech Europe as the industry representative body for *In-Vitro* Medical Devices (IVD) and Medical Devices (MD) manufacturers within Europe supports the application of Harmonised Standards under the new IVD and MD Regulations. Harmonised Standards are a key vehicle for the industry to ensure safe and effective products within the new legislative framework. The latest draft Standardisation Request (SReq) circulated by the European Commission in February 2019 includes a list of standards to be considered for harmonisation under each regulation and also proposes individual timelines for their adoption by the European Standards Organisations (ESO).

Following a detailed assessment of the proposed draft SReq by both the IVD and MD standards expert teams within MTE, a number of critical concerns were identified. They are outlined in detail below under Annex I.

- 1) Annexes I and II of the SReq (which outline standards candidates for harmonisation), lack several key horizontal standards that are vital to ensure safety and performance of devices.
- 2) Annexes I and II also specify when adoption of a standard by the ESOs is required – these timelines appear to be misaligned with the enforcement dates of the new regulations.
- 3) Specifying the editions of standards in the SReq hinders manufacturers from complying with applicable EU regulations.
- 4) Such a closed list of standards hinders CE-marking of innovative devices.
- 5) The number of the HArmonised Standards (HAS) consultants, who are engaged in the adoption process of standards for the entire medical technologies sector, is not sufficient compared to the number of standards to be assessed.
- 6) The current Annex III of the draft SReq halts the harmonisation of standards which reproduce the requirements set out in the respective regulations.

Any SReq which follows the current draft will result in a deficiency or a limited number of harmonised standards. This situation will lead to a lack of alignment between Notified Bodies with respect to the conformity assessment process and potential confusion within the system as a whole possibly allowing non-state of the art products to enter the market.

MedTech Europe calls upon the Member States, Notified Bodies and Standards Organisations to make representation to the European Commission to emphasise the potential long-term impact on product

availability, product approval, product safety and product innovation with a direct consequence to patient safety and delivery of state-of-the-art healthcare to patients across the European Union.

ANNEX I

- 1) Annexes I and II of the SReq outline standards candidates for harmonisation. These lists of standards for both IVDs and MDs, lack several key horizontal standards that are vital to ensure safety and performance of devices. Of note, the references to these standards are already listed in the Official Journal of the EU under the current medical devices' directives, e.g. IEC 61326-1 (EMC for IVDs), IEC 61010 series (Safety for laboratory equipment), ISO 14708 (Safety of active implants), ISO 14630 (Safety of non-active implants), ISO 17664 (Cleaning and disinfection of medical devices).
- 2) Annexes I and II also specify the timing of when adoption of a standard by the ESOs is required – these timelines appear to be misaligned with the enforcement dates of the new regulations. For example, the EN 60601 series related to basic safety and essential performance of MDs are due to be adopted by 27/5/2024, which is four years after the date of application of the MDR on 26/5/2020.
- 3) A SReq which specifies the editions of standards hinders manufacturers from complying with applicable EU regulations. IVD and MD manufacturers need to conform to the General Safety and Performance Requirements of IVD and MD Regulations, taking into account the generally acknowledged state-of-the-art. It may be possible that state-of-the-art would not be considered if manufacturers were to apply the edition of a standard referenced in the current Annexes I or II. Hence, the European Commission's focus on the standards editions is not in line with their responsibility to ensure that harmonised standards are "safe".
- 4) Such a closed list of standards hinders CE-marking of innovative devices. Given the time-intensive process to approve an SReq, such a closed list hinders the harmonisation of newly developed standards necessary for new technologies which are invented and developed in the best interest of delivering modern healthcare to EU citizens.
- 5) The number of the HARmonised Standards (HAS) consultants, who are engaged in the adoption process of standards for the entire medical technology's sector, is not appropriate to the number of standards to be assessed before they can be considered for final evaluation and publication by the European Commission. Of note, a total of 104 standards are currently listed in Annexes I and II, whereas the vast majority is due by May 2024.

The current Annex III of the draft SReq halts the harmonisation of standards which reproduce the requirements set out in the respective regulations. This approach would require extensive rewriting of standards to ensure no cross-over or the exclusion of standards only because of editorial issues.

It will also require extensive cross-referencing between regulations and standards with the potential for confusion.

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.

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