Sailab MedTech Finland

1st October 2025

The European Commission's Call for Evidence consultation in the context of the targeted MDR/IVDR reform.

Sailab – MedTech Finland is a trade association for in vitro medical devices and medical devices. Sailab – MedTech Finland is also a member of MedTech Europe.

Sailab – MedTech Finland proposes six revisions:

1. **Reduce the administrative burden**
   - The requirements for clinical investigations/perfomance studies should be made more risk-proportionate
   - Notified Body conformity assessment should be streamlined and mandatory recertification should be discontinued
   - Post-market surveillance reporting should be made more risk-proportionate
     - PMS obligation also applies, under Article 120, to devices manufactured as MDD during the transition period, EVEN IF production of the device is discontinued before it is brought into conformity with the MDR (e.g. because the PMS requirements introduced by the MDR create costs that can no longer be covered without new sales of the device). EVEN IF the device has never caused any incidents or been suspected of a product defect. This places manufacturers – and devices themselves – in different positions, since when production ends, the entire business may also cease operations (in which case there would no longer be an entity responsible for PMS activities throughout the entire device lifecycle)
2. **Enhance predictiblity of the certification processes of notified bodies**
   - The timelines for conformity assessment should be made more transparent and predictable
   - The cost of services of NBs should be made more transparent and predictable
   - A clearer definition of substantial change needed: any modification that could adversely impact 1) the safety/performance of medical device, 2) intended purpose or its prescribed conditions for use, 3) the manufacturer's QMS compliance with the legislative requirements
3. **Confirmity assessment requirements should be more proportionate**
   - Simplified confirmity assessment for low-to-medium-risk devices
   - Notified body bottlenecks need to be addressed with proportional oversight and resource allocation
   - Establish fast-track assessments for low-risk and well-established technologies
     i. E.g., MDR and IVDR removed the so-called "grandfathering" principle. Accordingly, if a product based on the same technology had been on the market without incidents, its MDD/IVDD-compliant technical documentation could still be used under the MDR/IVDR
4. **Further digitalisation is needed**
   - Extension of eIFU for certain MD lay use devices – e.g.when layuser receives guidance from their healthcare professional and the device is frequently used
   - Enabling the use of digital labels to provide information (e.g. Importer or Auth Representative contact details)
     i. Importer or Auth Representative contact details are needed for incident or product failure reporting – but if the Single Registration Number of manufacturer,

authorised rep and importer were used on packages instead of physical address, then the up-to-date contact details would be available for anyone via EUDAMED (MFR and AR are already via the UDI-DI, but as Importer is changing, perhaps this would only be useful for that.)

- Enabling digitalisation of the Technical Documentation with a unified data structure.
    i. This would increase internal/external efficiency. Manufacturers could gain insights into the data items that have been most effectively reused across products and accepted by Notified Bodies
    ii. Employing a consistent data structure, duplication of work is minimised, also making translations and version control easier to maintain
- Digitalisation (e.g. IFU, digital labels) promotes environmental aspects

5. International cooperation needed to promote competitiveness of the EU medical device sector

- Review the value of EU joining MDSAP and recognising MDSAP for CE marking
- Allocating resources to support EU competitiveness and enhance trust on CE marking by increasing international regulatory cooperation
- Adopt uniform Certificate of Free Sale until EUDAMED is fully operational to enhance reliance on CE marking – some countries not recognising CFS issued by certain EU countries (e.g., Finland)

6. Align MDR/IVDR better with other relevant legislation

- Green and sustainability legislation (e.g., REACH)
- HTA regulation
- Digital and Data Legislation
    - AI Act, EHDS, Data Act
    - Align GDPR with MDR/IVDR by clarifying lawful bases for processing personal data in clinical investigations, perfomance studies and post-market surveillance. E.g., MDR/IVDR must always take precedence over GDPR to ensure traceability of devices

Helsinki 1st October 2025
Anna Anttinen
Chief Executive Officer
Sailab – MedTech Finland