



European Union

Statement

WHO

156th Executive Board

(3-11 February 2025)

Agenda item 11- Standardisation of medical devices nomenclature

Geneva, 5 February 2025

WHO

156th Executive Board

Agenda item 11- Standardisation of medical devices nomenclature

Chair,

Director-General,

Excellencies,

Colleagues,

I have the honour of delivering this statement on behalf of the EU and its Member States.

The candidate countries North Macedonia, Montenegro, Serbia, Ukraine, Republic of Moldova, Bosnia and Herzegovina* and Georgia, the EFTA country Norway, member of the European Economic Area, as well as Armenia align themselves with this statement.

We thank the Director-General and the Secretariat for the report and for the continuous work on this topic.

The EU remains committed to advancing global harmonisation in medical device nomenclature and fostering regulatory convergence to improve patient safety, enhance healthcare systems, and support global regulatory reliance on EU medical device certificates. The EU also welcomes the work of the WHO in this area, particularly its work in uptake of the European Medical Device Nomenclature (EMDN) and other nomenclatures in its publications and platforms such as Meddevis.

The EMDN establishes a clear, accessible, and publicly available nomenclature system for medical devices. It has been developed through a transparent and collaborative process, informed by a global public consultation that included invaluable contributions from the World Health Organization (WHO). Unlike many existing systems, the EMDN is freely available for use and download by all stakeholders, exemplifying the EU's commitment to equity, inclusivity, and global health.

* North Macedonia, Montenegro, Serbia and Bosnia and Herzegovina continue to be part of the Stabilisation and Association Process.

In parallel with the EMDN, the EU has been developing the European database on medical devices (EUDAMED), a database designed to enhance transparency, traceability, and regulatory oversight in the medical device sector. As EUDAMED will be mandatory to use, on a gradual basis starting from next year, the EMDN can be used in EUDAMED to view all registered EU devices and review their certificates.

The EU and its Member States further recall that the EMDN is a clear, transparent, free nomenclature that is available to all States and which meets the criteria for global public goods. The EU is committed to supporting WHO Member States and providing access to this global public good.

Thank you.