

Statement on behalf of the Republic of Moldova
156th Executive Board Session
Agenda Item 11: Standardization of Medical Devices Nomenclature

Mr. Chair, Excellencies, Distinguished Delegates,

The Republic of Moldova welcomes the report presented by the Director-General on the standardization of medical devices nomenclature and acknowledges the progress made in implementing decision WHA75(25).

Moldova aligns itself with the statement delivered on behalf of the European Union.

We recognize the critical role of standardized medical devices nomenclature in enhancing patient safety, improving healthcare delivery, and strengthening health system resilience.

Two years ago, Moldova initiated a thorough modernization of the medical system with diagnostic and treatment medical equipment, which requires the regulation of this sector and the alignment with international standards. The Medical Devices Law is currently being developed.

At present, the national medical device registration system uses the GMDN nomenclature (Global Medical Device Nomenclature). Our Medicines and Medical Devices Agency (AMDM) manages the National Medical Device Registry that includes both device names and GMDN codes, contributing to their traceability on the market. The Agency has access to the GMDN database.

Thus, we support the WHO initiative to provide free access to database for all relevant actors in the field of medical devices, which will contribute to the transparency and efficiency of the process.

We particularly commend the integration of the European Medical Device Nomenclature (EMDN) and the Global Medical Device Nomenclature (GMDN) into the WHO Medical Devices Information System (MeDevIS). This step represents a significant advancement in ensuring a harmonized, accessible, and reliable system for medical device classification worldwide.

Moldova wishes to highlight the following key areas for focused attention:

- **Strengthening Accessibility and Interoperability**
 - o Ensuring that all Member States, including low- and middle-income countries, can effectively access and utilize MeDevIS for procurement, regulatory processes, and supply chain management.
 - o Enhancing interoperability between MeDevIS and other WHO platforms, including the Universal Health Coverage Compendium, the WHO Model List of Essential In Vitro Diagnostics, and national health information systems.
- **Capacity Building and Technical Support** through organizing training sessions and knowledge-sharing platforms to facilitate best practices
- Aligning medical device selection criteria with emerging health challenges.
- **Ensuring Open Access and Sustainability**

I thank you.