

The European Medical Device Nomenclature (EMDN)

The European Medical Device Nomenclature (EMDN) will be the nomenclature of use by manufacturers when registering their medical devices in the EUDAMED database.

Founded on pre-established criteria and requirements¹ and based on orientations provided by the Medical Device Coordination Group (MDCG), the European Commission decided in favour of the use of the '*Classificazione Nazionale Dispositivi medici* (CND)'² as the basis for the EMDN.

Currently, an extraordinary revision of the CND is ongoing so that to release the first version of the EMDN, which will be integrated in EUDAMED for use by operators. The EMDN will be fully available and accessible to any operators and will be copyright free.

To the extent possible, the Commission will map the EMDN to the Global Medical Device Nomenclature (GMDN). This task has been undertaken with the hopes of possibly facilitating EMDN code search by operators currently using GMDN. The correspondence between the nomenclatures is intended to be visible to operators and incorporated in the future database in the form of a searching tool. Therefore, and in cooperation with GMDN, the mapping exercise is currently ongoing. The level of quality and reliability of this mapping is dependent on the commitment of all relevant parties to work together in mapping and validating the results.

A sub-group of the MDCG on nomenclature which includes experts from National Competent Authorities and stakeholders has been established to oversee regulatory activities linked to nomenclature. The sub-group will aim to define the rules and processes related to the creation, update, maintenance and use of the European Medical Device Nomenclature.

Additionally, the Commission is currently collaborating with the World Health Organisation (WHO) in the context of their work and activities on a future international medical device nomenclature.

¹ (MDCG 2018-2) – 1

² CND is currently us



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