

Medical Devices Nomenclature

According to Article 26 of Regulation 745/2017 on medical devices and Article 23 of Regulation 746/2017 on in-vitro diagnostic medical device, the Commission is required to make available a medical device nomenclature to support the functioning of the future EUDAMED.

The relevant Commission services, in order to exert its faculty with the maximum possible level of knowledge and information and having due regard to the role held by the Medical Device Coordination Group (MDCG) under the new Regulations on medical devices, have established, in cooperation with the MDCG, a process which included the

1. Establishment of a task-force of Member States, operating under the UDI Work Group, supporting the relevant Commission services in the information gathering process and evaluation of options;
2. Endorsement by the MDCG of a document ([MDCG 2018-2](#)), providing a description of the requirements and criteria for the new nomenclature arising from the new Regulations on medical devices;
3. Evaluation by the relevant Commission services, in cooperation with the task-force, of possible options;
4. Production by the task-force of a report for consideration and discussion by the MDCG;

This process has come to completion and relevant discussions took place at the MDCG meetings of 30 November 2018 and 14-15 February 2019.

In accordance with Articles 23 IVDR and 26 MDR, having due regard to the views provided by the MDCG, **the CND nomenclature, to be mapped to the GMDN nomenclature, will be made available in the future Eudamed.**

The correspondence between the nomenclatures will be visible to operators and incorporated in the future database. This will allow all operators registering their device to find CND nomenclature equivalent to a GMDN code. To the purpose of providing better regulatory oversight over the EU nomenclature system, a sub-group of the Medical Device Coordination Group (MDCG) will be soon established.

Ways will also be explored to support the work that the World Health Organisation (WHO) is carrying out in the field.

Any additional informational on the details related to the governance and operational functioning of the system will be provided in the course of the next few months.