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EUROPEAN COMMISSION PUBLISHES UPDATED VERSION OF FUNCTIONAL SPECIFICATIONS FOR EUDAMED AND DECIDES THAT ITALIAN CND NOMENCLATURE WILL BE USED IN EUDAMED

The Medical Device Regulation ("**MDR**"), which will replace the current Medical Device Directive, provides for the establishment of the European database on medical devices ("**Eudamed**"). The European Commission recently took different decisions in respect of Eudamed:

Updated version of functional specifications for Eudamed

The objective of Eudamed is to increase transparency and traceability of medical devices. The database comprises the different electronic systems that exist under the MDR (e.g. UDI-database, electronic system on the registration of economic operators, electronic system of vigilance, electronic system on certificates of conformity).

Eudamed should be fully functional as of 26 May 2020, i.e. the application date of the MDR.

The European Commission has set up a plan for the (timely) implementation of Eudamed, in order to make sure that the database is fully functional, and considered as such by an independent audit report, by March 2020. As part of this plan, the European Commission has published an updated version of the functional specifications for Eudamed.

These functional specifications in essence comprise an overview of all the functionalities and requirements that Eudamed must entail and meet in accordance with the MDR. They form an essential part of the process leading up to the creation and implementation of Eudamed by the European Commission.

The updated version of the functional specifications for Eudamed can be consulted via this link.

Italian CND Nomenclature will be used in Eudamed

In the context of the future Eudamed article 26 of the MDR stipulates that the European Commission must ensure that *"an internationally recognised medical devices nomenclature is available free of charge to manufacturers and other natural or legal persons required by this Regulation to use that nomenclature".*

In this respect, the European Commission has decided that the Italian CND nomenclature (*Classificazione Nazionale dei Dispositivi Medicic*) will be used under the MDR. This means that the current GMDN nomenclature (*Global Medical Device Nomenclature*) will no longer be used in the future.

In order to facilitate the transition from the GMDN to the CND nomenclature, the Commission will provide a document that illustrates the similarities and differences between both nomenclatures. This should enable all operators to find (future) CND nomenclature equivalent to a (current) GMDN code.

The European Commission decision to use the CND nomenclature can be found via this link. The below websites and documents contain additional information about the CND nomenclature:

- The website of the Italian government regarding the CND nomenclature (in Italian) can be found via this link.
- The most recent version of the CND nomenclature of 13 March 2018 (in Italian) can be found via this link.

- An unofficial English translation of previous version of the CND nomenclature of 8 June 2016 can be consulted via this link.

We selected the above topics, given the importance of the MDR and the future functioning of Eudamed for the business of the ADDE members.

We hope this information is useful. You should not hesitate to contact us should you have any questions or require further information.

Kind regards,

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