MDCG 2019-1

MDCG guiding principles for issuing entities rules on Basic UDI-DI

January 2019

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law. In order to ensure, to the maximum possible extent, the quality of the code value entered in Eudamed, the Basic UDI-DI requirements on format should be as close as possible to the ones for the UDI-DI. In particular,

- the Basic UDI-DI code value shall have maximum 25 characters, so that it does not differ too significantly from the maximum length of the UDI-DI as established by the issuing entities;
- a check digit/character must be part of the Basic UDI-DI, based on an algorithm defined by the issuing entity. This algorithm shall be provided by the issuing entities to the Commission and to the manufacturers.