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

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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.

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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.