Commission Implementing Decision (EU) 2019/939 of 6 June 2019 designating issuing entities designated to operate a system for the assignment of Unique Device Identifiers (UDIs) in the field of medical devices (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2019/939

of 6 June 2019

designating issuing entities designated to operate a system for the assignment of Unique Device Identifiers (UDIs) in the field of medical devices

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC[(1)], and in particular the first subparagraph of Article 27(2) thereof,

Having regard to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU[(2)], and in particular the first subparagraph of Article 24(2) thereof,

Whereas:

(1) Article 27(1) of Regulation (EU) 2017/745 and Article 24(1) of Regulation (EU) 2017/746 each establish a Unique Device Identification system (UDI system) for certain medical devices falling within the scope of those Regulations.

(2) Before devices to which the UDI system applies are placed on the market, the manufacturer is required to assign a Unique Device Identifier (UDI) to the device and, if applicable, to all higher levels of packaging. The UDI has to be one that was created in compliance with the rules of an issuing entity designated by the Commission to operate a system for the assignment of UDIs. Manufacturers can only use coding standards provided by issuing entities designated by the Commission.

(3) Article 27(2) of Regulation (EU) 2017/745 and Article 24(2) of Regulation (EU) 2017/746 lay down criteria that must be satisfied by issuing entities before they can be designated to operate a system for assignment of UDIs pursuant to that Regulation.

(4) A call for applications from issuing entities interested in being designated to operate a system for assignment of UDIs pursuant to Regulation (EU) 2017/745 and a system for assignment of UDIs pursuant to Regulation (EU) 2017/746 was launched on the Commission's website on 21 December 2018[(3)], with a deadline of 25 January 2019. Four applications were received. The Commission has evaluated each of those applications and concluded that the entities concerned satisfy the relevant criteria for

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2019/939. (See end of Document for details)*

designation under both Regulations. The Medical Device Coordination Group (MDCG) was also consulted and did not raise any objection.

(5) The entities listed in the Annex to this Decision should therefore be designated to operate a system for assignment of UDIs pursuant to Regulation (EU) 2017/745 and a system for assignment of UDIs pursuant to Regulation (EU) 2017/746.

(6) The provisions of this Decision are closely linked since Regulation (EU) 2017/745 and Regulation (EU) 2017/746 both deal with medical devices and the UDI systems under both Regulations are closely related and are both subject to identical requirements. Since the same issuing entities are to be designated to operate a system for assignment of UDIs pursuant to Regulation (EU) 2017/745 and a system for assignment of UDIs pursuant to Regulation (EU) 2017/746, it is desirable to include the designations for both those Regulations in a single Decision,

HAS ADOPTED THIS DECISION:

Article 1

Designation of issuing entities

The issuing entities listed in the Annex to this Decision are designated to operate a system for assignment of UDIs pursuant to Regulation (EU) 2017/745 and to operate a system for assignment of UDIs pursuant to Regulation (EU) 2017/746.

Article 2

Terms of designation

1 The designations made under Article 1 shall each remain valid for a period of five years from 27 June 2019. At the end of that period, each of those designations may be renewed for a further period of five years if the issuing entity remain in compliance with the criteria for designation and the terms of designation.

2 The Commission may suspend or revoke the designation of an issuing entity under Article 1 at any time if it finds that the entity no longer satisfies the criteria for designation, laid down in the first subparagraph of Article 27(2) of Regulation (EU) 2017/745 or in the first subparagraph of Article 24(2) of Regulation (EU) 2017/746.

Article 3

Entry into force

This Decision shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European Union*.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2019/939. (See end of Document for details)*

Done at Brussels, 6 June 2019.

For the Commission

The President

Jean-Claude JUNCKER