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COMMISSION IMPLEMENTING DECISION (EU) 2024/2120

of 30 July 2024

renewing the designation of 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) Commission Implementing Decision (EU) 2019/939 ([3]) designated four issuing entities that satisfied the relevant criteria for designation under both Regulations (EU) 2017/745 and (EU) 2017/746 to operate a system for the assignment of Unique Device Identifiers (UDIs) in the field of medical devices. According to Article 2 of the Implementing Decision (EU) 2019/939, those designations shall each remain valid for a period of time of five years from 27 June 2019, and 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) By the end of the period of validity of those designations, the Commission assessed the compliance of the four designated entities with the relevant criteria for designation and the terms of designation. The Commission established that each of the four designated entities remains in compliance with the criteria for designation and the terms of designation.

(3) It is therefore appropriate to renew each of those designations for a further period of five years, starting from the end of validity of the previous designations in order to ensure full continuity in the operation of the UDI system,

HAS ADOPTED THIS DECISION:

Article 1

Renewal of designation of issuing entities

The designation of the issuing entities listed in the Annex to Implementing Decision (EU) 2019/939 is renewed for a period of five years from 27 June 2024 until 27 June 2029.

([1]) OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj.
([2]) OJ L 117, 5.5.2017, p. 176, ELI: http://data.europa.eu/eli/reg/2017/746/oj.
([3]) 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 (OJ L 149, 7.6.2019, p. 73, ELI: http://data.europa.eu/eli/dec_impl/2019/939/oj).

Article 2

Entry into force

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

Done at Brussels, 30 July 2024.

For the Commission
The President
Ursula VON DER LEYEN