



2025/788

28.7.2025

COMMISSION DELEGATED REGULATION (EU) 2025/788
of 16 April 2025
amending Delegated Regulation (EU) 2023/2197 as regards the date of application
(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⁾, in particular Article 27(10), point (b), thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) 2023/2197 ⁽²⁾ amended Regulation (EU) 2017/745 as regards the assignment of Unique Device Identifiers (UDI) for contact lenses as highly individualised devices, by introducing the 'Master UDI-DI' solution. Delegated Regulation (EU) 2023/2197 is to apply from 9 November 2025.
- (2) The Subgroup on Unique Device Identification of the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745 identified a need to develop guidance to ensure effective and harmonised implementation of the Master UDI-DI solution for contact lenses.
- (3) The MDCG endorsed guidance document MDCG 2024-1 'Guidance on the implementation of the Master UDI-DI solution for contact lenses'. The Commission published that guidance document on its website in November 2024 ⁽³⁾, one year before the date of application of Delegated Regulation (EU) 2023/2197.
- (4) Given the clear need for availability of that guidance document for operators to plan their implementation efforts and resource allocation on such complex technical matter, in order to allow them to adequately implement the Master UDI-DI solution for contact lenses and adapt their internal systems and technologies for UDI assignment, as well as to ensure the necessary level of legal certainty on the market and a smooth transition to the new rules, it is appropriate to defer the date of application of Delegated Regulation (EU) 2023/2197 by one year.
- (5) Delegated Regulation (EU) 2023/2197 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

In Delegated Regulation (EU) 2023/2197, Article 2, the second paragraph is replaced by the following:

'It shall apply from 9 November 2026.'

⁽¹⁾ OJ L 117, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>.

⁽²⁾ Commission Delegated Regulation (EU) 2023/2197 of 10 July 2023 amending Regulation (EU) 2017/745 of the European Parliament and of the Council, as regards the assignment of Unique Device Identifiers for contact lenses (OJ L, 2023/2197, 20.10.2023, ELI: http://data.europa.eu/eli/reg_del/2023/2197/oj).

⁽³⁾ https://health.ec.europa.eu/document/download/c8c6cca5-460e-410e-a325-be08bfc7dea6_en?filename=mdcg_2024-14_en.pdf.

Article 2

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

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 16 April 2025.

For the Commission
The President
Ursula VON DER LEYEN
