

DECISION OF THE EEA JOINT COMMITTEE
No 198/2025

of 19 September 2025

**amending Annex II (Technical regulations, standards, testing and certification) to the
EEA Agreement**

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area (“the EEA Agreement”), and
in particular Article 98 thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2025/117 of 24 January 2025 laying down rules for the application of Regulation (EU) 2021/2282 with regard to the procedures for joint scientific consultations on medical devices and *in vitro* diagnostic medical devices¹ is to be incorporated into the EEA Agreement.
- (2) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Annex II to the EEA Agreement is amended as follows:

1. The following point is inserted after point 23a (Commission Implementing Regulation (EU) 2024/1381) of Chapter XIII:
‘23b. **32025 R 0117**: Commission Implementing Regulation (EU) 2025/117 of 24 January 2025 laying down rules for the application of Regulation (EU) 2021/2282 with regard to the procedures for joint scientific consultations on medical devices and *in vitro* diagnostic medical devices (OJ L, 2025/117, 27.1.2025).’
2. The following point is inserted after point 17a (Commission Implementing Regulation (EU) 2024/1381) of Chapter XXX:
‘17b. **32025 R 0117**: Commission Implementing Regulation (EU) 2025/117 of 24 January 2025 laying down rules for the application of Regulation (EU) 2021/2282 with regard to the procedures for joint scientific consultations on medical devices and *in vitro* diagnostic medical devices (OJ L, 2025/117, 27.1.2025).’

Article 2

The text of Implementing Regulation (EU) 2025/117 in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

¹ OJ L, 2025/117, 27.1.2025, ELI: http://data.europa.eu/eli/reg_impl/2025/117/oj

Article 3

This Decision shall enter into force on 20 September 2025, provided that all the notifications under Article 103(1) of the EEA Agreement have been made*.

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 19 September 2025.

*For the EEA Joint Committee
The President*

Stefán Haukur Jóhannesson

*The Secretaries
To the EEA Joint Committee*

Knut Hermansen

Matúš Minárik

* No constitutional requirements indicated.