



2023/2338

26.10.2023

DECISION OF THE EEA JOINT COMMITTEE No 49/2023

of 17 March 2023

amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement  
[2023/2338]

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) 2022/944 of 17 June 2022 laying down rules for the application of Regulation (EU) 2017/746 of the European Parliament and of the Council as regards the tasks of and criteria for European Union reference laboratories in the field of *in vitro* diagnostic medical devices <sup>(1)</sup> is to be incorporated into the EEA Agreement.
- (2) Commission Implementing Regulation (EU) 2022/945 of 17 June 2022 laying down rules for the application of Regulation (EU) 2017/746 of the European Parliament and the Council with regard to fees that may be levied by EU reference laboratories in the field of *in vitro* diagnostic medical devices <sup>(2)</sup> is to be incorporated into the EEA Agreement.
- (3) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The following points are inserted after point 12a (Commission Implementing Regulation (EU) 2022/1107) of Chapter XXX of Annex II to the EEA Agreement:

- ‘12b. **32022 R 0944**: Commission Implementing Regulation (EU) 2022/944 of 17 June 2022 laying down rules for the application of Regulation (EU) 2017/746 of the European Parliament and of the Council as regards the tasks of and criteria for European Union reference laboratories in the field of *in vitro* diagnostic medical devices (OJ L 164, 20.6.2022, p. 7).
- 12c. **32022 R 0945**: Commission Implementing Regulation (EU) 2022/945 of 17 June 2022 laying down rules for the application of Regulation (EU) 2017/746 of the European Parliament and the Council with regard to fees that may be levied by EU reference laboratories in the field of *in vitro* diagnostic medical devices (OJ L 164, 20.6.2022, p. 20).’

Article 2

The texts of Implementing Regulations (EU) 2022/944 and (EU) 2022/945 in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on 18 March 2023, provided that all the notifications under Article 103(1) of the EEA Agreement have been made \*.

<sup>(1)</sup> OJ L 164, 20.6.2022, p. 7.

<sup>(2)</sup> OJ L 164, 20.6.2022, p. 20.

\* No constitutional requirements indicated.

*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, 17 March 2023.

*For the EEA Joint Committee*  
*The President*  
Nicolas VON LINGEN

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