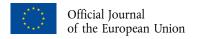
26.10.2023



# 2023/2338

### **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:

- 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 (1) 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 (2) 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.

<sup>\*</sup> No constitutional requirements indicated.

EN OJ L, 26.10.2023

## 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