



2023/2331

26.10.2023

**DECISION OF THE EEA JOINT COMMITTEE No 48/2023**

**of 17 March 2023**

**amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement  
[2023/2331]**

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) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices <sup>(1)</sup> is to be incorporated into the EEA Agreement.
- (2) Commission Implementing Regulation (EU) 2022/2347 of 1 December 2022 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards reclassification of groups of certain active products without an intended medical purpose <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 11c (Commission Implementing Regulation (EU) 2021/2078) of Chapter XXX of Annex II to the EEA Agreement:

- ‘11d. **32022 R 2346**: Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices (OJ L 311, 2.12.2022, p. 60).
- 11e. **32022 R 2347**: Commission Implementing Regulation (EU) 2022/2347 of 1 December 2022 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards reclassification of groups of certain active products without an intended medical purpose (OJ L 311, 2.12.2022, p. 94).’

*Article 2*

The texts of Implementing Regulations (EU) 2022/2346 and (EU) 2022/2347 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 311, 2.12.2022, p. 60.

<sup>(2)</sup> OJ L 311, 2.12.2022, p. 94.

\* 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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