

DECISION OF THE EEA JOINT COMMITTEE No 134/2022
of 29 April 2022
amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement
[2022/1578]

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) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices ⁽¹⁾ is to be incorporated into the EEA Agreement.
- (2) Implementing Regulation (EU) 2021/2226 repeals Commission Regulation (EU) No 207/2012 ⁽²⁾, which is incorporated into the EEA Agreement and which is consequently to be repealed under the EEA Agreement.
- (3) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Chapter XXX of Annex II to the EEA Agreement shall be amended as follows:

- (1) the text of point 9 (Commission Regulation (EU) No 207/2012) is deleted;
- (2) the following point is inserted after point 11a (Commission Implementing Decision (EU) 2019/1396):

'11b. **32021 R 2226**: Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices (OJ L 448, 15.12.2021, p. 32).'

Article 2

The text of Implementing Regulation (EU) 2021/2226 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 30 April 2022, provided that all the notifications under Article 103(1) of the EEA Agreement have been made ⁽³⁾.

⁽¹⁾ OJ L 448, 15.12.2021, p. 32.

⁽²⁾ OJ L 72, 10.3.2012, p. 28.

⁽³⁾ 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, 29 April 2022.

For the EEA Joint Committee
The President
Nicolas VON LINGEN
