

DECISION OF THE EEA JOINT COMMITTEE
No 242/2022

of 23 September 2022

**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) 2021/2078 of 26 November 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the European Database on Medical Devices (Eudamed)¹ 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

The following is inserted after point 11b (Commission Implementing Regulation (EU) 2021/2226) of Chapter XXX of Annex II to the EEA Agreement:

- ‘11c. **32021 R 2078:** Commission Implementing Regulation (EU) 2021/2078 of 26 November 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the European Database on Medical Devices (Eudamed) (OJ L 426, 29.11.2021, p. 9).

The provisions of the Regulation shall, for the purposes of this Agreement, be read with the following adaptation:

Notwithstanding the provisions of Protocol 1 to this Agreement, and unless otherwise provided for in this Agreement, the terms Member State(s) and competent authorities shall be understood to include, in addition to their meaning in the Regulation, the EFTA States and their competent authorities, respectively.’

Article 2

The text of Implementing Regulation (EU) 2021/2078 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 426, 29.11.2021, p. 9.

Article 3

This Decision shall enter into force on 24 September 2022, 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, 23 September 2022.

*For the EEA Joint Committee
The President*

Kristján Andri Stefánsson

*The Secretaries
To the EEA Joint Committee*

Siri Veseth Meling Matúš Minárik

* No constitutional requirements indicated.