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DECISION OF THE EEA JOINT COMMITTEE No 15/2023

of 3 February 2023

amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement [2023/2307]

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) 2022/1107 of 4 July 2022 laying down common specifications for certain class D *in vitro* diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council [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 point is inserted after point 12 (Regulation (EU) 2017/746 of the European Parliament and of the Council) of Chapter XXX of Annex II to the EEA Agreement:

'12a. **32022 R 1107**: Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D *in vitro* diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council (OJ L 178, 5.7.2022, p. 3).'

Article 2

The text of Implementing Regulation (EU) 2022/1107 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 4 February 2023, 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, 3 February 2023.

For the EEA Joint Committee
The President
Nicolas VON LINGEN

[1] OJ L 178, 5.7.2022, p. 3.

* No constitutional requirements indicated.