THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area (‘the EEA Agreement’), and in particular Article 98 thereof,

Whereas:


(2) Regulation (EU) 2017/745 repeals, with effect from 26 May 2020, Council Directives 90/385/EEC (²) and 93/42/EEC (³) which are incorporated into the EEA Agreement and are therefore to be repealed under the Agreement with effect from 26 May 2020.

(3) Annexes I and II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1


Article 2

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


(2) The following is inserted after point 10 (Commission Implementing Regulation (EU) No 920/2013) of Chapter XXX:


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

(a) The EFTA States shall participate fully in the Medical Device Coordination Group (MDCG) established under Article 103, but shall not have the right to vote.

(b) The EFTA States shall participate in the European database on medical devices (Eudamed) set up by the Commission as referred to in Article 33.


Article 3

The text of Regulation (EU) 2017/745, as corrected by OJ L 117, 3.5.2019, p. 9, 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 4

This Decision shall enter into force on 14 December 2019, or on the day following the last notification to the EEA Joint Committee under Article 103(1) of the EEA Agreement have been made (*), whichever is the later.

Article 5

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, 13 December 2019.

For the EEA Joint Committee

The President

Gunnar PÁLSSON

(*) Constitutional requirements indicated.