Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance)

CHAPTER V

CLASSIFICATION AND CONFORMITY ASSESSMENT

Section 2

Conformity assessment

Article 55

Certificate of free sale

1 For the purpose of export and upon request by a manufacturer or an authorised representative, the Member State in which the manufacturer or the authorised representative has its registered place of business shall issue a certificate of free sale declaring that the manufacturer or the authorised representative, as applicable, has its registered place of business on its territory and that the device in question bearing the CE-marking in accordance with this Regulation may be marketed in the Union. The certificate of free sale shall set out the Basic UDI-DI of the device as provided to the UDI database under Article 26. Where a notified body has issued a certificate pursuant to Article 51, the certificate of free sale shall set out the unique number identifying the certificate issued by the notified body, as referred to in Section 3 of Chapter II of Annex XII.

2 The Commission may, by means of implementing acts, establish a model for certificates of free sale, taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 107(2).