**Statement**

**of the EU-Turkey Customs Union Joint Committee**

**on the implementation of Decision 1/2006 of the EC-Turkey Association Council**

Having regard to Decision 1/2006 of the EC-Turkey Association Council, and in particular Articles 1, 6(e) thereof and Article 52 of Decision 1/95 of the EC-Turkey Association Council;

Whereas:

Article 3(3) of Decision No 1/95 of the EC-Turkey Association Council states that the customs territory of the Customs Union shall comprise the customs territory of the Community as defined in the Community Customs Code and the customs territory of Turkey;

As the Union instruments subject to a statement by the Customs Union Joint Committee and the corresponding Turkish provisions giving effect to it contain notions or make references to procedures specific for the European Union or Turkish legal order, it is necessary to apply the horizontal understanding included in Annex I of Decision 2/97 also to these instruments in order to ensure the correct application of the procedure included in Article 1 of Decision 1/2006 and thus the full effectiveness of that Decision.

The Customs Union Joint Committee recognises that the Turkish legislation has taken over all the comments submitted by the Commission and is therefore aligned with the EU acquis and that Turkey has put into force the provisions of the Union instrument necessary for the elimination of the technical barriers to trade in the products covered by the following:

> 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

The Customs Union Joint Committee therefore notes that Article 9 of Decision 1/95 of the EC-Turkey Association Council would be implemented with respect to the scope of the EU instrument listed above.

Whenever the EU instrument listed above and the relevant Turkish provisions giving effect to that instrument contain references to the territories of the Parties, the references shall, for the purpose of Decision No 1/95 of the EC-Turkey Association Council, be understood to comprise the territory of the EU-Turkey Customs Union.

The above EU instrument would be subject to horizontal adaptations set out in Annex I of Decision 2/97 of the EC-Turkey Association Council.

Whenever the relevant Turkish provisions giving effect to the above EU instrument contain references to nationals of the Republic of Turkey, the references would be understood to be references also to nationals of the EU Member States.

Notwithstanding the present Statement, in order to affix the CE marking to the products, it is necessary to transpose all relevant EU harmonisation legislation providing for the affixing of the CE marking in order to ensure that products to which it has been affixed fulfill all applicable EU harmonised requirements. In addition, Turkey shall take decisions to implement all Commission delegated and implementing acts under the In Vitro Diagnostic Medical Devices Regulation.

The Turkish legislation which relates to Regulation (EU) 2017/746, including any procedures set out in that legislation, shall be applied in line with the related or corresponding provisions of that Regulation.

To conform to the EU's data protection legislation governing access by Turkish authorities (and other operators, if applicable) to the European database on medical devices (Eudamed), an Administrative Arrangement has been concluded between the Commission and Turkey pursuant to Article 48-3b of the Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data. This statement is valid as long as the Administrative Arrangement remains in force.

**For the European Commission** **For the Republic of Turkey**

Date 13/09/2021