EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
DIRECTORATE GENERAL FOR NEIGHBOURHOOD AND ENLARGEMENT NEGOTIATIONS

Brussels,
March 2022

NOTICE TO STAKEHOLDERS

EU-TURKEY CUSTOMS UNION AGREEMENT IN THE FIELD OF MEDICAL DEVICES

The establishment of the Customs Union of the EU and Turkey has been done gradually. Following Decisions Nos 1/95, 2/97 and 1/2006 of the EC-Turkey Association Council, the EU-Turkey Customs Union Joint Committee confirmed in its statements of 21 May 2021 and 13 September 2021 on the implementation of Decision 1/2006 of the EC-Turkey Association Council that Turkish legislation is aligned with:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and

- 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 two statements of 21 May 2021 and 13 September 2021 further confirm that "*Whenever the EU instrument listed above [i.e. Regulations 2017/745 or 2017/746] 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.*"

In light of this, the following conclusions with regard to authorised representatives and notified bodies can be drawn:[1]

I. Authorised representative[2]

1. Manufacturers established within the territory of the Customs Union

Manufacturers established in the EU have no obligation to designate an authorised representative in Turkey in order to place devices on the Turkish market. *Vice versa*,

[1] The same conclusions were already drawn with regard to the previous medical devices Directives, see Interpretative document of the Commission Services of 11 February 2020 – Interpretation of the Customs Union Agreement with Turkey in the field of medical devices (Ref. Ares(2015)2026339).

[2] For the definition of 'authorised representative' see Article 2(32) MDR/Article 2(25) IVDR; for designation and change see Articles 11, 12 MDR/IVDR.

manufacturers established in Turkey have no obligation to designate an authorised representative on the EU territory in order to place medical devices on the EU market.

2. Manufacturers established outside the territory of the Customs Union

Decision No 1/2006 states that an authorised representative has to be nominated "*in Turkey **or** in the Community*". Therefore, manufacturers established outside the territory of the EU or Turkey only need to designate one authorised representative, either in the EU or in Turkey, in order to place medical devices on the market in the EU or in Turkey.

II. Notified body[3]

1. Notified bodies in Turkey

Turkey is entitled to designate notified bodies in accordance with Regulations 2017/745 and 2017/746. In addition, following Article 2(1) of Decision No 1/2006 concerning the notification of Turkish conformity assessment bodies, it is possible for Turkey to designate more than one notified body.

2. Certification by a Turkish notified body

A notified body established in Turkey has the same rights and obligations as a notified body established in the EU. Medical devices covered by a certificate duly issued by a Turkish notified body may circulate freely in the EU. *Vice versa*, medical devices covered by a certificate duly issued by a notified body established in the EU may circulate freely in Turkey.

Annex 1: Statement of the EU-Turkey Customs Union Joint Committee on the implementation of Decision 1/2006 of the EC-Turkey Association Council of 21.5.2021 (concerning Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices) (Ref. Ares(2021)3455199)

Annex 2: Statement of the EU-Turkey Customs Union Joint Committee on the implementation of Decision 1/2006 of the EC-Turkey Association Council of 13.9.2021 (concerning Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices) (Ref. Ares(2021)5903963)

[3] For the definition of 'notified body' see Article 2(42) MDR/Article 2(34) IVDR.

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

Myriam FERRAN
Director
DG NEAR
European Commission

For the Republic of Turkey

Hüsnü DILEMRE
Director General
Directorate General of International Agreements and EU Affairs
Ministry of Trade

Date 13/09/2021

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) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

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 fulfil all applicable EU harmonised requirements. In addition, Turkey shall take decisions to implement all Commission delegated and implementing acts under the Medical Devices Regulation.

The Turkish legislation which relates to Regulation (EU) 2017/745, 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 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

[redacted]

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For the Republic of Turkey

[redacted]

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Directorate General of International Agreements and EU Affairs
Ministry of Trade

Date 21/05/2021