NEW MEDICAL DEVICE REGULATIONS

As it is known, in accordance with Articles 8 to 11 of Decision No 1/95 of the EU-Turkey Association Council establishing the Customs Union between Turkey and the European Union (EU), it had been decreed that Turkey should include the EU's technical legislation on products into its domestic law. Following this, the technical legislation that Turkey needs to harmonize was listed by Decision No 2/97 of the EU-Turkey Association Council and the public institutions that carry out the harmonization processes were determined by Decision No 97/9196 of the Ministers Council.

In this context; Law No 4703 on the "Preparation and Implementation of Technical Legislation on Products"[1], prepared by the Ministry of Trade (Ministry of Economy), entered into force on 11 January 2002, and based on the aforementioned law, pursuant to Decision No 97/9196 of the Ministers Council, the harmonization studies of the 3 basic Directives of the European Union on medical devices were started by our Ministry. As a result of relevant studies;

• The Directive dated 20 June 1990 and numbered 90/385/EEC on Active Implantable Medical Devices was harmonized and published in the Official Gazette dated 12 March 2002 and numbered 24693, with the name of "Regulation on Active Implantable Medical Devices",

• The Directive dated 14 June 1993 and numbered 93/42/EEC on Medical Device was harmonized and published in the Official Gazette dated 13 March 2002 and numbered 24694, with the name of "Medical Device Regulation",

• The Directive dated 27 October 1998 and numbered 98/79/EC on in vitro Medical Diagnostic Devices was harmonized and published in the Official Gazette dated 14 October 2003 and numbered 25259, with the name of "Regulation on Medical Diagnostic Devices Used outside the Body (*in vitro*)".

With the publication of these regulations, compliance with the directives in the European Union was achieved in the placing of medical devices on the market in our country. In this way, it became possible for our citizens to reach the products manufactured in accordance with global regulations, and in addition, it was paved the way for medical devices manufactured in our country to be exported to EU member states without being subject to any additional certification or licensing.

In this period in which the European Union medical device legislation began to be implemented in our country pursuant to the Customs Union, with Decision No 1/2006 of the EU-Turkey Association Council published in 2006, the obligation of our manufacturers to appoint authorised representatives in the EU Member States was removed. In addition, with the aforementioned decision, it became also possible to designate notified bodies, which are very important for the manufacturing ecosystem, by Turkey. In this way, the first notified body was designated in our country in 2009, and thus our manufacturers had the opportunity to receive certification activities from notified bodies established in our country.

The relevant regulations have been in force for about 30 years in the European Union and for 18 years in our country. Within the scope of the aforementioned regulations, the requirements to be met by the products to be placed on the market have been determined, but

[1] The Law dated 5/3/2020 and numbered 7223 on Product Safety and Technical Regulations; replaced the Law on the Preparation and Implementation of the Technical Legislation on Products on 5/3/2021.

with the continuous development of technology, innovative products have emerged in the field of medical devices, as in almost every field. In this context, the EU Commission started a study in 2010, and in 2012, the proposals presented by the EU Commission to the EU Parliament and the Council and the current directives were decided to be revised as Regulations.

In this context, the legislation updated to comply with current technology and living standards, and the "Regulation (EU) 2017/745 on Medical Devices", in order to replace the Directives on Active Implantable Medical Devices and on Medical Devices, and the "Regulation (EU) 2017/746 on in vitro Diagnostic Medical Devices", in order to replace the Directive on In Vitro Diagnostic Medical Devices, were published in the EU Official Journal on 05 May 2017 and entered into force in the EU as of 26 May 2017.

The Medical Device Regulation fully implemented in the EU and in our country, simultaneously as of 26 May 2021. The In vitro Diagnostic Medical Device Regulation will be fully implemented as of 26 May 2022.

In accordance with the new regulations, the Regulations dated 07/06/2011 and numbered 27957 on Medical Device and on Active Implantable Medical Devices have been repealed, except for the transitional provisions specified in Article 108 of the Regulation.

Additionally, "*In vitro* Diagnostic Medical Device Regulation" prepared in parallel with the "*In vitro* Diagnostic Medical Devices Regulation (EU) 2017/746" was published in the Official Gazette on 02.06.2021, except for some provisions of the relevant Regulation that came into force as of 26.05.2021, other provisions will enter into force as of 26/05/2022.

By these newly published regulations, it is aimed to protect the health and safety of patients and users at a high level, supply high-quality medical devices, support innovation, and create a transparent, robust and sustainable medical device market.

In this context; in accordance with the regulations in question, economic operators, manufacturers, authorised representatives and importers in our country will also register in the EUDAMED database. The obligations and requirements related to EUDAMED will apply 6 months after the Commission publishes a notice in the EU Official Journal that EUDAMED is fully functional and meets its functional specifications. EUDAMED is scheduled to be officially launched on May 26, 2022, however, the module on Actor Registration is currently available on a voluntary basis. In the coming days, economic operators in Turkey will also be able to notify the actor registration module.

Until EUDAMED is fully functional, the regarding provisions of the Regulations dated 07/06/2011 and numbered 27957 on Medical Device and on Active Implantable Medical Devices, will continue, especially including relevant information on vigilance reporting, clinical investigations, registration of devices and of economic operators and certificate notifications.

In addition, with the Medical Device Regulation, some product groups have been included in the regulation, the definition of a medical device has been expanded and prognostic devices have begun to be defined as medical devices.

Again, with the new regulations, class changes are foreseen for some products. In particular, some class I medical devices may have been up-classified, and thus a notified body audit and EC certificate will be required for placing these products on the market. A new subclass named class I reusable devices (class Ir) has been created for product groups such as

surgical instruments. According to the current regulation, products such as disposable surgical instruments, etc. placed into the market as class I have been brought to a higher level of scrutiny by the new regulation. In this context, after the relevant transition period, manufacturers will not be allowed to place on the market medical devices within the class Ir category only with a declaration of conformity, and the new regulations require a notified body audit and EC certificate for such products.

In this direction;

1. Medical devices, which are classified as class I other according to the Medical Device Regulation published in the Official Gazette dated 07/06/2011 and numbered 27957 and are classified as class I other pursuant to the new regulations, can be placed on the market in accordance with the new regulations as of 26/05/2021.

2. Devices that are classified as class I is other according to the Medical Device Regulation published in the Official Gazette dated 07/06/2011 and numbered 27957 , but are up-classified (Class Ir, class Im, Class Is, class IIa, Class IIb and Class III) according to the newly published regulations, and devices with a valid certificate issued in accordance with the Medical Device Regulation and the Regulation on Active Implantable Medical Devices published in the Official Gazette dated 07/06/2011 and numbered 27957, provided that they will continue to comply with the aforementioned Regulations as of 26/05/2021 and there is no significant change in the design and intended use of the devices in question, may be placed on the market until 26/05/2024, and may be made available on the market or continue to be put into service until 26/05/2025. However, even if they continue to comply with the aforementioned regulations and there is no significant change in the design and intended use of the device in question, medical devices within the scope of this article will not be allowed to be placed on the market after 26/05/2024 and will not be possible to be made available on the market as of 26/05/2025.

3. Although some exceptions regarding placing on the market have been defined in the relevant regulations for the devices specified in the first and second articles, the manufacturers and importers of such products will ensure that these products meet the requirements regarding post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices in accordance with the new regulations.

4. On the other hand, certificates issued by notified bodies within the scope of the Medical Device Regulation and Active Implantable Medical Devices Regulation published in the Official Gazette dated 07/06/2011 and numbered 27957, provided that **there is no significant change in the design or purpose of use** of the products except for EC Certificates issued within the scope of Annex IV, will remain valid until 27/05/2024. Certificates issued under Annex IV will remain valid until 27/05/2022. Within the scope of such validity period, the notified body issuing the certificate will continue to be responsible for the

necessary surveillance of all applicable requirements regarding the devices it has certified.

5. In accordance with the Medical Device Regulation and the Regulation on Active Implantable Medical Devices published in the Official Gazette dated 07/06/2011 and numbered 27957, medical devices that were placed on the market legally in our country and EU market before 26/05/2021, may continue to be made available on the market or put into service until 26/05/2025 in compliance with the registration requirements specified by the Agency.

The conditions regarding the validity of the certificates and conditions for benefiting from the transitional provisions regarding the placing on the market of the devices have been specified in detail in the Guidance Documents with the reference of MDCG 2020-2. Rev.1, MDCG 2020-3. Rev.1 and MDCG 2020-3, published by the Commission.

In addition, the principles regarding the Product Tracking System – Ürün Takip Sistemi (ÜTS) registration notifications of the related products during the transition period have also been announced on the website of our Institution, and the relevant documents are available at https://www.titck.gov.tr/duyuru/yeni-tibbi-cihaz-tuzugu-nun-yururluge-girdiginde-urun-takip-sistemi-nde-uts-yurutulecek-urun-kayit-ve-tekil-hareket-surecleri-26052021115427

In addition to all these changes, with the new regulations, some product groups specified in Annex XVI of the Regulation, which are not medical devices but similar to medical devices in terms of risk profile, are also included in the scope of the Medical Device Regulation.

The obligations regarding the product groups mentioned above and listed in Annex XVI will apply as from the date of entry into force of the common specifications to be published by the EU Commission. Until this date, the placing of the aforementioned products on the market will be carried out in accordance with the regulations to which they are currently subject, and as of the date of application of the common specifications specified in the relevant product group, the related products will also have to be placed on the market in accordance with the specified regulations. The common specifications will enter into force 6 months after the publication of the common specifications in the relevant field by the EU Commission, and it is of great importance for the manufacturers of the relevant products to ensure compliance with the current requirements within the specified period in terms of placing the products on the market.

Respectfully brought to the attention of the public.