**Announcement No. 2023/KK-1**

**on the Implementation of the Provisions of Regulation (EU) No. 2023/607**

As is known, as part of the efforts for full harmonization with the current medical device legislation of the European Union (EU), the “Regulation on Medical Devices” and the “Regulation on In Vitro Diagnostic Medical Devices”, which are fully compliant with the Medical Devices Regulation (MDR) No. (EU) 2017/745 and the In Vitro Diagnostic Medical Device Regulation (IVDR) No. (EU) 2017/746, were published in the Official Gazette dated 2/6/2021 with the number 31499 (Repeated) and entered into force.

In order to reduce the risk of non-supply of medical devices, the European Commission has published the *“Regulation (EU) 2023/607 of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices”* in the Official Journal of the EU on **20 March 2023**, with effect from **20 March 2023**.

In this context, devices under the Directive 90/385/EEC or Directive 93/42/EEC may be placed on the market or put into service until:

1. **May 26, 2026** for Class III implantable custom-made medical devices,
2. **December 31, 2027** for Class III devices and Class IIb implantable devices excluding sutures, staples, dental fillings, dental brackets, dental crowns, screws, wedges, plates, wires, pins, clips and connectors,
3. **December 31, 2028** for class IIb devices other than those covered above, class IIa devices and class I devices placed on the market in sterile condition or with a measuring function,
4. **December 31, 2028** for devices for which the conformity assessment procedure under Directive 93/42/EEC does not require the involvement of a notified body, for which a declaration of conformity was issued before May 26, 2021 and for which the conformity assessment procedure under the MDR requires the involvement of a notified body,

provided that they fulfill the conditions set out in this Regulation.

**PART-I**

**Application Procedures and Principles for Devices Referred to in (A)**

For placing the devices referred to in **(A)** on the market in our country and registering them in the Product Tracking System (ÜTS), the necessary applications must be made as per the procedures and principles listed below:

* 1. Provided that an application is made to a notified body appointed within the scope of Regulation (EU) 2017/745 (MDR) before 26.05.2024; an application must be made without physical documents via the Application Document Type “***Application for an Extension No. 2023/KK-1***” on ebs.titck.gov.tr
     1. including a declaration containing the minimum points specified in **Annex-1** that the extension conditions are met by the manufacturer, and
     2. a document confirming that the application has been accepted by the notified body authorized by the MDR
  2. Provided that a contract is concluded with a notified body appointed under Regulation (EU) 2017/745 (MDR) before 26.09.2024; an application must be made without physical documents via the Application Document Type ***“Application for an Extension No. 2023/KK-1”*** on ebs.titck.gov.tr
     1. including a declaration containing the minimum points specified in **Annex-1** that the extension conditions are met by the manufacturer, and
     2. a document containing the minimum points specified in **Annex-2** issued by the notified body authorized under MDR.
  3. In the event that the application made pursuant to the first article of this Part is deemed appropriate following the necessary confirmation procedures, the period of registration in the ÜTS of the device(s) covered by the relevant application shall be extended until 26.09.2024.
  4. In the event that the application made pursuant to the second article of this Part is deemed appropriate following the necessary confirmation procedures, the period of registration in the ÜTS of the device(s) covered by the relevant application shall be extended up to the periods specified in the Medical Devices Regulation (until 26.05.2026).
  5. Software development processes for the activities on the ÜTS of the devices for which an extension is approved pursuant to the third to fourth articles of this Part are ongoing, and upon completion of these works, a new Announcement on the application procedures to be carried out by the companies on the ÜTS will be published. Companies will need to apply to the ÜTS based on the Announcement to be published to define the appropriate time extension processes in the ÜTS.

**PART-II**

**Application Procedures and Principles for Devices Referred to in (B) and (C)**

For placing the devices referred to in **(B)** and **(C)** on the market in our country and registering them in the Product Tracking System, the necessary applications must be made as per the procedures and principles listed below:

* 1. No extension will be applicable for products covered by an **EC certificate with an expiration date before 26.05.2021** issued by a notified body authorized under Directive 93/42/EEC or Directive 90/385/EEC.
  2. For the devices covered by an **EC certificate with an expiration date after 26.05.2021** issued by a notified body authorized under Directive 93/42/EEC or Directive 90/385/EEC; an application must be made without physical documents via the Application Document Type ***“Application for an Extension No. 2023/KK-1”*** on ebs.titck.gov.tr,
     1. If the manufacturers of the devices covered by the EC certificate with an expiration date before 20.03.2023,
        1. have applied to a notified body appointed under Regulation (EU) 2017/745 (MDR) before the expiration date of the certificate and signed a contract with this notified body, following documents shall be enclosed;
           1. a declaration containing the minimum points specified in **Annex-1** that the extension conditions are met by the manufacturer,
           2. a document containing the minimum points specified in **Annex-2** issued by the authorized notified body under MDR.
           3. A document issued by the notified body issuing the current EC certificate that the surveillance responsibility for the devices covered by the EC certificate issued under Directive 93/42/EEC or Directive 90/385/EEC until 26.09.2024 has been taken or by the contracted notified body per MDR in case of taking that responsibility
        2. have signed a contract with a notified body appointed under Regulation (EU) 2017/745 (MDR) after the expiration date of the certificate, following documents shall be enclosed;
           1. a document containing the minimum points specified in **Annex-2** issued by the notified body authorized under MDR.
           2. An authorization certificate from our Agency under Article 59 of the Medical Devices Regulation (Article 59 MDR) or an authorization certificate from our Agency or the relevant Competent Authority under Article 94 of the Medical Devices Regulation (Article 97 MDR)
     2. If the manufacturers of the devices covered by the EC certificate with an expiration date on or after 20.03.2023,
        1. have not applied to a notified body appointed under Regulation (EU) 2017/745 (MDR), following documents shall be enclosed;
           1. a declaration containing the minimum points specified in **Annex-1** that the extension conditions are met by the manufacturer, and
           2. A document issued by the notified body issuing the current EC certificate that the surveillance responsibility for the devices covered by the EC certificate issued under Directive 93/42/EEC or Directive 90/385/EEC until 26.05.2024 has been taken.
        2. Provided that an application is made to a notified body appointed within the scope of Regulation (EU) 2017/745 (MDR) before 26.05.2024, following documents shall be enclosed;
           1. a declaration containing the minimum points specified in **Annex-1** that the extension conditions are met by the manufacturer,
           2. a document confirming that the application has been accepted by the notified body authorized per MDR, and
           3. A document issued by the notified body issuing the current EC certificate that the surveillance responsibility for the devices covered by the EC certificate issued under Directive 93/42/EEC or Directive 90/385/EEC until 26.09.2024 has been taken
        3. Provided that an application is made to a notified body appointed under Regulation (EU) 2017/745 (MDR) before 26.05.2024 and a contract is concluded with that notified body before 26.09.2024, following documents shall be enclosed;
           1. a declaration containing the minimum points specified in **Annex-1** that the extension conditions are met by the manufacturer,
           2. a document containing the minimum points specified in **Annex-2** issued by the notified body authorized under MDR.
           3. A document issued by the notified body issuing the current EC certificate that the surveillance responsibility for the devices covered by the EC certificate issued under Directive 93/42/EEC or Directive 90/385/EEC until 26.09.2024 has been taken or the contracted notified body per MDR in case of taking that responsibility.
  3. In the event that the application made pursuant to paragraph a of the second article of this Part is deemed appropriate following the necessary confirmation procedures, the EC certificate(s) covered by the relevant application shall be extended for the periods specified in the Medical Devices Regulation (until 31.12.2027 or 31.12.2028, depending on the device risk class).
  4. In the event that the application made pursuant to;
* subparagraph (i) of paragraph (b) of the second article of this Part is deemed appropriate following the necessary confirmation procedures, the EC certificate(s) covered by the relevant application shall be extended until 26.05.2024;
* subparagraph (ii) of paragraph (b) of the second article of this Part is deemed appropriate following the necessary confirmation procedures, the EC certificate(s) covered by the relevant application shall be extended until 26.09.2024;
* subparagraph (iii) of paragraph (b) of the second article of this Part is deemed appropriate following the necessary confirmation procedures, the EC certificate(s) covered by the relevant application shall be extended for the periods specified in the Medical Devices Regulation (until 31.12.2027 or 31.12.2028, depending on the device risk class)
  1. Software development processes for the activities on the ÜTS of the EC certificates for which an extension is approved pursuant to the third to fourth articles of this Part are ongoing, and upon completion of these works, a new Announcement on the application procedures to be carried out by the companies on the ÜTS will be published. Companies will need to apply to the ÜTS based on the Announcement to be published to define the appropriate time extension processes in the ÜTS.

**PART-III**

**Application Procedures and Principles for Devices Referred to in (D)**

For placing the devices referred to in **(D)** on the market in our country and registering them in the Product Tracking System, the necessary applications must be made as per the procedures and principles listed below:

* 1. Provided that an application is made to a notified body appointed within the scope of Regulation (EU) 2017/745 (MDR) before 26.05.2024; an application must be made without physical documents via the Application Document Type “***Application for an Extension No. 2023/KK-1***” on ebs.titck.gov.tr
     1. including a declaration containing the minimum points specified in **Annex-1** that the extension conditions are met by the manufacturer, and
     2. a document confirming that the application has been accepted by the notified body authorized by the MDR
  2. Provided that a contract is concluded with a notified body appointed under Regulation (EU) 2017/745 (MDR) before 26.09.2024; an application must be made without physical documents via the Application Document Type ***“Application for an Extension No. 2023/KK-1”*** on ebs.titck.gov.tr
     1. including a declaration containing the minimum points specified in **Annex-1** that the extension conditions are met by the manufacturer, and
     2. a document containing the minimum points specified in **Annex-2** issued by the authorized notified body under MDR.
  3. In the event that the application made pursuant to the first article of this Part is deemed appropriate following the necessary confirmation procedures, the period of registration in the ÜTS of the device(s) covered by the relevant application shall be extended until 26.09.2024.
  4. In the event that the application made pursuant to the second article of this Part is deemed appropriate following the necessary confirmation procedures, the period of registration in the ÜTS of the device(s) covered by the relevant application shall be extended up to the periods (until 31.12.2028) specified in the Medical Devices Regulation.
  5. Software development processes for the activities on the ÜTS of the devices and their declarations of conformity for which an extension is approved pursuant to the third to fourth articles of this Part are ongoing, and upon completion of these works, a new Announcement on the application procedures to be carried out by the companies on the ÜTS will be published. Companies will need to apply to the ÜTS based on the Announcement to be published to define the appropriate time extension processes in the ÜTS.

**Announcement No. 2023/KK-1 Annex-1**

**Annex-1**

**Minimum Requirements for the Declaration to be Prepared by the Manufacturer that the Conditions for Extension are Met**

1. A statement that the device(s) concerned remains in conformity with Directive 90/385/EEC or Directive 93/42/EEC (whichever Directive is applicable),
2. A statement that no significant change has been made to the design and intended use of the relevant device(s),
3. A statement that the relevant device(s) does not pose an unacceptable risk to the health or safety of patients, users or other persons, or to other issues relating to the protection of public health,
4. A statement that a quality management system (QMS) in accordance with Article 10(9) of the MDR will be in place no later than May 26, 2024 (if a QMS has been implemented before May 26, 2024, the statement should include relevant details),
5. In accordance with the first subparagraph of Article 4.3 of Annex VII of the MDR for the conformity assessment of the device(s) concerned or the device(s) intended to replace the device(s) concerned, a statement that the manufacturer or its authorized representative has submitted or will submit a formal application to a notified body no later than May 26, 2024 (application details including date of application, approval details, scope of application should also be included in the declaration),
6. A statement that a written agreement has been or will be signed between the relevant notified body and the manufacturer in accordance with the second subparagraph of Article 4.3 of Annex VII of the MDR, no later than September 26, 2024 (the details of the agreement including the date of the agreement, approval details, devices covered by the agreement should also be included in the statement),
7. To confirm the validity of this declaration, contact information, including e-mail address of the authorized person of the manufacturing company issuing the declaration.

**Announcement No. 2023/KK-1 Annex-2**

**Annex-2**

**Minimum Requirements for the Document (Confirmation Letter) to be issued by the Authorized Notified Body within the Scope of MDR**

1. A statement that the conformity assessment application of the manufacturer has been received by the relevant notified body (this document must include the date of application, manufacturer information and information on the acceptance of the application (including the date of acceptance of the application)),
2. A statement that, after the application, a written agreement has been signed by the manufacturer and the relevant notified body in accordance with the second subparagraph of Article 4.3 of Annex VII of the MDR (the date of the agreement must be specified in the document),
3. Detailed information on the devices that are covered by the agreement and will benefit from the extension and a list of the relevant devices (in the relevant document, the devices covered by the agreement must be listed in a clear and descriptive manner to avoid any doubt),
4. For the devices referred to in (B) and (C) of this Announcement, information on EC Certificates under the agreement (including the notified body issuing the certificate and the number of the EC Certificate),
5. To confirm the validity of this confirmation letter, contact information, including the e-mail address of the authorized person of the notified body issuing the document.