MDR TRANSITION PERIOD

With Regulation (EU) 2023/607, the validity periods of MDD certificates have been extended provided that certain conditions are met.

January,2024

INFORMATION NOTE

about

THE EXTENSION OF VALIDITY PERIODS OF MDD CERTIFICATES

and

THE MDR TRANSITION PROCESS

Regulations **(EU) 2017/745 (MDR)** and **(EU) 2017/746 (IVDR)** set high standards of quality and safety for medical devices and in vitro diagnostic medical devices to meet common safety concerns regarding such devices.

In order to reduce the risk of non-supply of medical devices, European Commision published "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 EU Official Journal on 20 March 2023.

L 80/24 EN Official Journal of the European Union 20.3.2023

REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 March 2023

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices

(Text with EEA relevance)

"Even though the transition period has been extended with the Regulation, UDEM A.Ş. recommends that manufactures who have not yet submitted their MDR application or started their project should not postpone their MDR transition plans. As stated in the guidance MDCG 2022-11; it is specifically stated that it is beneficial for the manufacturer to apply to a notified body for MDR certification at least one year before the expiry of the validity period of Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD). Although there are specific deadlines for the MDR application and contract within the scope of the transition period conditions, delays in the submission of applications or documentation means that there will be backlog and capacity problems, and therefore the risk of delays in the conformity assessment process."

Devices covered by the MDD/AIMDD certificate or declaration of conformity issued before 26 May 2021 may be placed on the market or put into service until the dates detailed in Table-1, provided that they meet the following conditions.

- Maintaining compliance with Directive 93/42/EEC;
- No significant change in design and intended use;
- The device does not pose an unacceptable risk to the health and safety of patients, users, other persons or the public health;

- The manufacture has a quality management system in accordance with the MDR established before 26 May 2024;
- The manufacturer or its Authorised Representative must have made an official application to a Notified Body authorised under the MDR for the relevant devices or new generation devices of these devices in accordance with the scope of Section 4.3 of Annex VII of the MDR before the certificate validity date (26 May 2024 at the latest) and a contract has been signed between the Notified Body and the manufacturer in accordance with the scope of Section 4.3 of Annex VII of the MDR before the certificate validity date (26 September 2024 at the latest).

or

- The Competent Authority of a Member State must have accepte an exception to the applicable conformity assessment procedure in accordance with Article 59(1) of the MDR or has requested the manufacturer to carry out the applicable conformity assessment procedure in accordance with Article 97(1) of the MDR

Table-1: Transition periods according to medical device risk classes

RISK CLASS	TRANSITION PERIOD
✓ Class III devices ✓ Class IIb implantable devices excluding well-established technology	December 31, 2027
✓ Other class IIb devices ✓ Class IIa devices ✓ Class I devices placed on the market in sterile condition or with a measuring function ✓ Devices that did not require a notified body previously but require a notified body with the MDR	December 31, 2028

well-established technology IIb implants*: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors*

The above-mentioned conditions are intended to guarantee that the manufacturer has taken the necessary action regarding the MDR transition.

In order to benefit from the extension, the following documents are required;

- Self-declaration of **the manufacturer** indicating that it fulfils the requirements set out in the Regulation
- Confirmation letter issued by the **MDD notified body** indicating that it has taken responsibility for surveillance audit
- Confirmation letter indicating that there is an MDR application / contract issued by the **MDR notified body**

Below are the 2 most common situations that summarize Regulation:

Manufacturers who have transitioned to the MDR and hold an MDD Certificate issued from 25 May 2017, still valid on 26 May 2021, not subsequently withdrawn and still valid on the date of publication of Regulation (EU) 2023/607 (20 March 2023), are allowed to continue to place older devices on the market until 26 May 2024, provided that the following conditions are met.

- Device continues to be comply with MDD
- No significant changes in the design and intended purpose of the device
- The devices do not present an unacceptable risk to the health or safety of patients and users

Additionally, if the following additional conditions are met, legacy devices can benefit from the validity period specified in Table-1 for the MDD Certificate:

- Manufacturers must implement an MDR compliant QMS and submit a formal application to a Notified Body for an MDR Conformity Assessment by 26 May 2024 at the latest.
- No later than 26 September 2024, a formal agreement has been signed with a Notified Body in relation to the device or substitute device covered by the expired certificate

A surveillance audit should be applied for devices within the MDD certificate.

Manufacturers who have tansitioned to the MDR and hold an MDD Certificate issued from 25 May 2017, still valid on 26 May 2021 and expiring before 20 March 2023, are allowed to continue to place legacy devices on the market and benefit from extended transition periods until 26 May 2024 only if one of the following conditions are met.

- The Competent Authority granted a derogation/exemption under Article 59(1) or Article 97(1) of the MDR before March 20, 2023

OR

- The manufacturer applies for MDR and signs a formal written agreement with a Notified Body for MDR before the expiry of this MDD Certificate in respect of the device covered by the expired certificate or a device intended to replace that device

Additionally, if the following additional conditions are met, legacy devices can benefit from the validity period specified in Table-1 for the MDD Certificate:

- Manufacturers must implement an MDR compliant QMS and submit a formal application to a Notified Body for an MDR Conformity Assessment by 26 May 2024 at the latest.
- No later than 26 September 2024, a formal agreement has been signed with a Notified Body in relation to the device covered by the expired certificate or a device intended to replace that device

MDD Surveillance Audits within the Scope of Transition Period

Manufacturers that met the above conditions can extend the validity period of their MDD certificates provided that they fulfil the MDD requirements, in other words, MDD surveillance continues.

Manufacturers are required to submit the extension request to UDEM A.Ş. with the **UDFRM.305 Extension Process Information Form On EC Certificates Applicable Under 93/42/EEC** in order to verify the compliance of the relevant information with the conditions specified in Regulation (EU) 2023/607.

Unless the customer has agreed with a notified body under the MDR to perform MDD surveillance, UDEM A.Ş. remains responsible for appropriate surveillance in respect of the applicable requirements for the devices it certifies until **26 September 2024 at the latest**. After this date or, if agreed, as of the date of the MDR contract, the customer may request the MDR notified body to take over the surveillance responsibility. In this case, it is necessary to sign a tripartite contract between the customer, UDEM A.Ş. and the MDR notified body, which includes the necessary conditions regarding the transfer of surveillance and audit responsibility.

Likewise, manufacturers signing an MDR contract with UDEM A.Ş. have the right to transfer the responsibility of surveillance audit of valid MDD certificates, if any, to UDEM A.Ş. with a tripartite contract.

UDEM A.Ş. may conduct combined audits if the scope of the MDD certificate and the scope of the MDR contract overlap.

No extension will be applied for the products covered by the EC certificate issued by UDEM A.Ş. and whose certificate expiry date is before 26.05.2021.

For devices covered by the EC certificate issued by UDEM A.Ş. and valid on and after 26.05.2021;

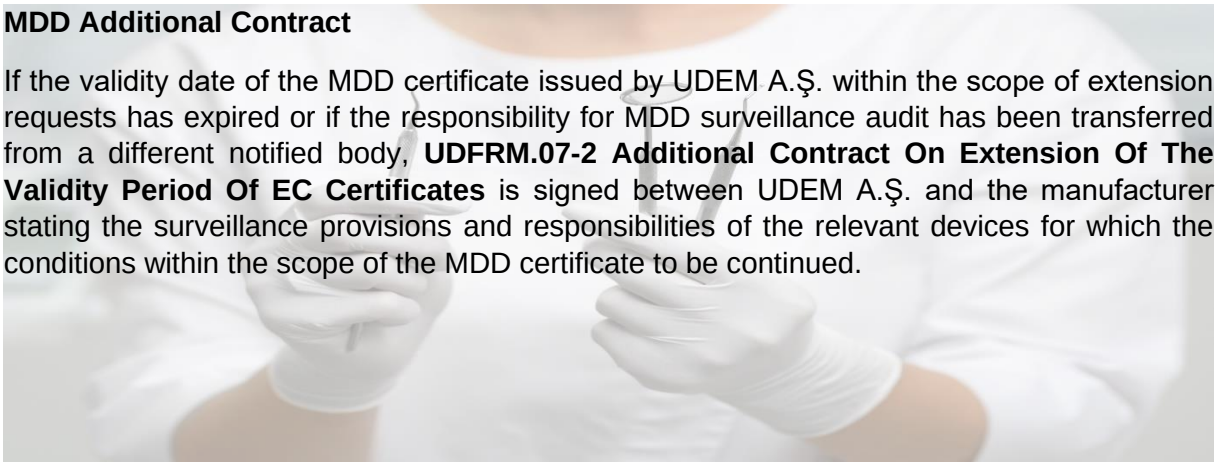
a. If the manufacturers of devices within the scope of the MDD certificate whose certificate expiration date is before 20.03.2023 have applied to a notified body assigned within the scope of MDR before the certificate expiration date and signed a contract with this notified body; If the devices within the scope of the MDR contract overlap with the devices in the MDD certificate, the surveillance processes of these devices until 26.09.2024 are carried out by UDEM A.Ş.

b. If the manufacturers of the devices covered by the MDD certificate, whose certificate expiry date will expire on or after 20.03.2023, have not applied to a notified body assigned within the scope of MDR; the surveillance processes regarding the devices covered by the MDD certificate until 26.05.2024 are carried out by UDEM A.Ş.

c. Provided that the manufacturers of the devices covered by the MDD certificate, whose certificate expiry date will expire on or after 20.03.2023, apply to a notified body assigned within the scope of MDR before 26.05.2024 and/or make a contract with this notified body before 26.09.2024; the surveillance processes regarding the devices covered by the MDD certificate until 26.09.2024 are carried out by UDEM A.Ş.

Where the MDR written agreement covers a device intended to substitute covered by the MDD certificate issued by UDEM A.Ş, the surveillance process shall be conducted in respect of the device that is being substituted (covered by the existing certificate).

MDD Additional Contract



If the validity date of the MDD certificate issued by UDEM A.Ş. within the scope of extension requests has expired or if the responsibility for MDD surveillance audit has been transferred from a different notified body, **UDFRM.07-2 Additional Contract On Extension Of The Validity Period Of EC Certificates** is signed between UDEM A.Ş. and the manufacturer stating the surveillance provisions and responsibilities of the relevant devices for which the conditions within the scope of the MDD certificate to be continued.

Notified Body Confirmation Letters

If the last surveillance audit of the customer has been performed by UDEM A.Ş. within the last year, an **MDD Extension Confirmation Letter** is issued to the customer stating that the surveillance audit responsibility is taken by UDEM A.Ş. according to their compliance with (EU) 2023/607 conditions. If more than one year has passed over the last surveillance date of the customer, the relevant extension letter is issued if the surveillance audit is carried out and no critical infrastructure non-conformity is detected.

In addition, **MDR Confirmation Letter** is also issued to the manufacturers whose official application is received or contract is signed within the scope of MDR.

For detailed information:

- Regulation (EU) 2023/607
  https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R0607
- TİTCK Regulation (EU) 2023/607
  https://www.titck.gov.tr/duyuru/tcokka-ab-2023-607-sayili-tuzuk-20032023160117
- Q&A- Regulation (EU) 2023/607
  https://health.ec.europa.eu/system/files/2023-07/mdr_proposal_extension-q-n-a.pdf
- TITCK translation- Regulation (EU) 2023/607
  https://titck.gov.tr/storage/Archive/2023/contentFile/mdr_proposal_extension-q-n-a_rev1_326213b5-7fcd-45bb-934f-3bac4eaacedf.pdf
- Flowchart Regulation (EU) 2023/607
  https://health.ec.europa.eu/system/files/2023-08/md_devices-art120_flowchart_0.pdf
- TİTCK Announcement – 2023/KK-5
  https://titck.gov.tr/storage/Archive/2023/announcement/2023KK5SaylDuyuru_9fdd66d3-afa0-44b2-b45b-6181221d197a.pdf