T.R.
MINISTRY OF HEALTH
Turkish Medicines and Medical Devices Agency

TÜRKİYE CUMHURİYETİNİN YÜZÜNCÜ YILI

Issue : E-61749811-511.99-1586151
Subject : 2023-KK-1

BAROTEK TIBBI MALZEME MEDIKAL URUNLER SU ALTI DALIS EKIPMANLARI SANAYI VE TICARET LTD. STI.
Esentepe Mah. Milangaz Cad., Bina No: 77 /1, Ic Kapi No: 64 Kartal ISTANBUL

Reference : Your letter dated 26.09.2024, numbered E-48535386-511.01.99-3402518, with transaction tracking 6273180

Your application requesting the extension of the validity period for the EC certificate numbered 2195-MED-401431701, which expires on 27.09.2024, has been reviewed.

The European Commission's "Regulation (EU) No 2023/607 of the European Parliament and of the Council, which amends Regulations (EU) 2017/745 and (EU) 2017/746 concerning transitional provisions for certain medical devices and in vitro diagnostic medical devices," was issued in the Official Journal of the EU on **20 March 2023** and took effect on the same date.

In alignment with the EU's current medical device legislation and in accordance with Regulation (EU) No. 2023/607 of the European Parliament and Council, our regulations titled "Regulation Amending the Regulation on Medical Devices" and "Regulation Amending the Regulation on Medical Devices for In Vitro Diagnostic Purposes" were published in the Official Gazette on **2/4/2023**. The aforementioned amendments were subsequently incorporated into the Regulation on Medical Devices and the Regulation on Medical Devices for In Vitro Diagnostic Purposes.

Additionally, to mitigate the risk of shortages of high-risk in vitro diagnostic medical devices (IVD), and provided that specific conditions are satisfied, the gradual mandatory implementation of the relevant modules will commence in the last quarter of 2025, immediately following the declaration of EUDAMED's operational status. A new requirement has also been introduced for advance notification in cases where disruptions in the supply of devices governed by the MDR and IVDR are anticipated, particularly for devices whose supply interruption is deemed to pose a serious risk to patients or public health. Regulation (EU) No 2024/1860 of the European Parliament and of the Council, dated 9 July 2024, which amends Regulations (EU) 2017/745 and (EU) 2017/746 concerning the phased implementation of EUDAMED, the obligation to provide notification of supply disruptions, and transitional provisions for certain in vitro diagnostic medical devices, was published in the Official Journal of the EU on **9 July 2024** and came into force.

In alignment with the EU's current medical device legislation and in accordance with Regulation (EU) No. 2024/1860, our "Regulation Amending the Regulation on Medical Devices for In Vitro Diagnostic Purposes" was published in the Official Gazette dated **17 August 2024**, No. **32635**. These amendments have been incorporated into our "Regulation on Medical Devices for In Vitro Diagnostic Purposes."

Pursuant to the aforementioned EU Regulations, our Announcement titled "Announcement Revising the Announcement No. 2024/KK-2 (2023/KK-1 Rev.2) No. 2023/KK-5," which details the procedures and principles for EBS applications in the implementation of the transitional provisions outlined in both Regulation (EU) 2023/607 and Regulation (EU) 2024/1860, was published on our Agency's website and the UTS Portal on 21 August 2024 and has come into effect.

This document has been signed with secure electronic signature.
Verification Code: ZW56Q3NRM0FyS3k0Z1AxQ3NRM0FySHY3 Verification Address: https://www.turkiye.gov.tr/saglik-titck-ebys

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In this regard, the relevant applications were reviewed under the "Announcement Revising the Announcement No. 2024/KK-2 (2023/KK-1 Rev.2) No. 2023/KK-5," and it was determined that extending the validity period of the EC certificate numbered 2195-MED-401431701 until **31.12.2028** is appropriate. Accordingly, pursuant to our Announcement titled "Announcement Revising Announcement **2024/KK-3** No. 2023/KK-2 in line with the provisions of Regulation (EU) 2024/1860," you are kindly requested to submit a document registration/update application in UTS and attach this response letter along with its annexes to the relevant application.

Kindly submitted for your information.

Dr. Mehmet Hakan FIRAT
On behalf of the Head of the Agency
Deputy Head of the Institution

ANNEXES:
1-Annex-1 (1 page)
2-Annex-2 (6 pages)

This document hereby was translated as complete and true by notary certified translator

İşbu Türkçe belge aslından İngilizce diline tam ve doğru tercüme edilmiştir

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