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S E R T İ F İ K A

CERTIFICATE

KALİTE YÖNETİMİ / *QUALITY MANAGEMENT*

EMSAŞ ELEKTRİK MALZEMELERİ SAN. VE TİC. A.Ş

kuruluşunun,
company,

Muradiye Sanayi Bölgesi Muradiye Mah. 28 Sok. No: 6
Yunus Emre / Manisa / Türkiye

adresinde,
at address,

ISITMA SİSTEMLERİ, ELEKTRİKLİ KOMBİ, TERMOBOYLER, TERMOSİFON, ISI POMPASI, SOĞUTMA SİSTEMLERİ, SANAYİ TİPİ SU SEBİLLERİ, SANAYİ VE EV TİPİ SOĞUTUCULAR DOLAPLAR, KAN SAKLAMA DOLABI, AŞI SAKLAMA DOLABI, TROMBOSİT İNKÜBATÖRÜ, AJİTATÖR, PLAZMA SAKLAMA DOLABI, PLAZMA ERİTME VE KAN ISITMA CİHAZI ÜRETİMİ, SATIŞI, İTHALAT VE İHRACATI

HEATING SYSTEMS, ELECTRIC BOILER, TERMOBOY ARE HEATING, HEAT PUMP, COOLING SYSTEM, INDUSTRIAL WATER DISPENSERS, DOMESTIC AND INDUSTRIAL REFRIGERATION CABINETS, BLOOD BANK REFRIGERATORS, VACCINE STORAGE CABINETS, PLATELET INCUBATOR, AGITATOR, PLASMA STORAGE CABINET, PLASMA MELTING AND BLOOD HEAT DEVICE PRODUCTION, SALES, IMPORT AND EXPORT

kapsamında
at scope

kalite yönetim sistemi yürürlüğe koyduğu,
perform the quality management system,

ISO 9001: 2015

standart taleplerinin yerine getirildiği belirlenmiştir.
the complete of the standard was determined.

İlk Yayın Tarihi	/ *Date First Registered*	: 12.10.2015
Yayın Tarihi	/ *Date Certificate Issued*	: 23.09.2024
Geçerlilik Periyodu	/ *Period of Registration*	: 3 Yıl / *Years*
Geçerlilik Tarihi	/ *Date Certificate Expires*	: 11.09.2025
Sertifika Numarası	/ *Certificate No*	: 01/11240/10

TÜRKAK
Kalite Yönetim Sistemi
TS EN ISO / IEC 17021
AB - 0060 - YS

TÜRKAK BDS NO
YS-6507-7316

Onay:
Approved by:

Bu sertifikanın geçerliliği, yılda en az bir kez yapılacak gözetim denetiminin başarılı geçmesine bağlıdır. Bu durumda belge yeniden düzenlenecektir.
The Validity of this certificate, subject to successful completion of surveillance audit which will take place at least once a year. In this case, the document will be revised.

SERTİFİKASYON ★ CERTIFICATION ★ ZERTIFIZIERUNG ★ СЕРТИФИКАЦИЯ
ASB

SZUTEST

CERTIFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 32104001

EMSAŞ ELEKTRİK MALZ. SAN. TİC. A.Ş.

Inönü Mahallesi 28 Sokak Muradiye Köyü Muradiye Bucağı 6 Dış Kapı No Merkez / Manisa /TÜRKİYE

EN ISO 13485:2016

Design, Production, Sales and Technical Service of Blood Bank Regrigerator, Thrombocyte Incubator, Thrombocyte Agitator, Blood Plasma Freezer and Vaccine Refrigerator

Approves that the Medical Devices Quality Management System implemented for above scope.

First Issue Date	09.02.2021
Issue Date	25.01.2024
Expiry Date	24.01.2027
Revision Date/No	25.01.2024 / 1

TÜRKAK BDS NO YS-e223-3348

TÜRKAK Tıbbi Cihazlar K. Y. S. TS EN ISO/IEC 17021 AB-0044-YS

Deputy General Manager

The certificate inquiry is made by reading the QR codes by mobile devices, providing necessary information on http://public.szutest.com.tr or by using BDS No on https://tdbs.turkak.org.tr.

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2024/05/16
CL1/V4a

Esteemed

EMSAŞ ELEKTRİK MALZEMELERİ SAN.TİC.AŞ.

İnonü Mahallesi 28 Sokak Muradiye Köyü Muradiye Bucağı 6 Dış Kapı No Manisa/Merkez , Türkiye

Notified Body Confirmation Letter Reference: CERBO0326724

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, Kiwa Cermet Italia S.p.a., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0476 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

EMSAŞ ELEKTRİK MALZEMELERİ SAN.TİC.AŞ.

İnonü Mahallesi 28 Sokak Muradiye Köyü Muradiye Bucağı 6 Dış Kapı No Manisa/Merkez, Türkiye

SRN Number (if available): not defined

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment

procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,
Dr.ssa Frabetti Alessia
Medical Device Division Manager

Alessia Frabetti

Firmato digitalmente da: ALESSIA FRABETTI
Data: 17/12/2024 19:27:37

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
BLOOD BANK REFRIGERATOR (869997506EKN3W)	Class IIa	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 2195-MED1732001 NB# 2195
TROMBOCYTE INCUBATOR (869997506ECI2U)	Class IIa	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 2195-MED1732001 NB# 2195
TROMBOCYTE AGITATOR (869997506EAJ2Q)	Class IIa	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 2195-MED1732001 NB# 2195
BLOOD PLASMA FREEZER (869997506EE9Q, 869997506EF9S)	Class IIa	Identification of the corresponding device under MDD ✓ Same □ Substitute	Certificate No: 2195-MED1732001 NB# 2195

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
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Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/16	Rev.00	Initial issue
2024/05/21	Rev.01	Adress Changed
2024/09/26	Rev.02	Responsibility for Appropriate Surveillance

For further information on the content of the letter or verification of the validity of the letter please contact medical@kiwa.com or phone at +39.051.4593.111