WQR
WORLD QUALITY REGISTRAR

CERTIFICATE

Emsaş Elektrik Malzemeleri Sanayi ve Tic. A.Ş.

Muradiye Mah. 28 (OSB) Sk. Emsaş No: 6 Yunusemre Manisa Türkiye

This certificate is issued for the above-mentioned company, according to the following scope given by the WQR Certification.

ISO 13485:2016

Medical Devices Quality Management System

Scope of Certification

Design, Production, Sales Marketing and Technical Service of Blood Cabinets, Platelet Incubators, Platelet Agitators, Plasma Storage Cabinets and Vaccine Cabinets, Ultra Low Freezer, Ice Line Cabinets, Breast Milk Storage Cabinets, Baby Bottle Warmers, Incubators, Plasma Heating, Serum Warming Cabinets, Oven, Refrigerated Incubators, Test Cabinets

World Accreditation Services
ACCREDITED
CERTIFICATION BODIES
EN ISO/IEC 17021

Certificate No : W-250547
Publication Date : 22.05.2025
Last Issue Date : 22.05.2025
Expiry Date : 21.05.2026

WQR International Certification Ltd.
Director

The validity of the certificate can be checked through www.wqrcert.com or www.the-was.com.

CERTIFICATE

EMSAŞ ELEKTRİK MALZEMELERİ SANAYİ VE TİCARET ANONİM ŞİRKETİ MANİSA ŞUBESİ

MURADİYE SANAYİ BÖLGESİ MURADİYE MAH. 28 SOK. NO:6
YUNUSEMRE / MANİSA / TÜRKİYE

Has been assessed and found to comply with the requirements of:
Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

ISO 45001:2018

The Occupational Health and Safety Management System is applicable to:
İş Sağlığı Ve Güvenliği Yönetim Sistemi:

PRODUCTION, SALES, IMPORT AND EXPORT OF HEATING SYSTEMS, ELECTRIC BOILER, THERMOBOILER, THERMOSIPHON, HEAT PUMP, COOLING SYSTEMS, INDUSTRIAL TYPE WATER DISPENSERS, INDUSTRIAL AND HOME TYPE COOLERS CABINETS, BLOOD STORAGE CABINET, VACCINE STORAGE CABINET, PLATELET INCUBATOR, AGITATOR, PLASMA STORAGE CABINET, PLASMA MELTING AND BLOOD WARMING DEVICE

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

Certificate Number: OHSMS-00113786
Belge Numarası: OHSMS-00113786

Initial Certification Date: 30.12.2023
İlk Belgelendirme Tarihi: 30.12.2023

Certification Period: 3 Years
Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 29.12.2024
Belge Geçerlilik Tarihi: 29.12.2024

IQR Sertifikasyon Onayı

ACCREDITED
Management Systems
Certification Body
MSCB-135

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.
Beşevler Mah. Kocayunus Sk. No:3 Arslan Han Plaza K:2 Nilüfer / BURSA
Tel.: +90.224.266 00 16 Faks: +90.224.249 41 13 www.iqrcert.com e-posta: info@iqrcert.com

SZUTEST

EC CERTIFICATE

AT SERTİFİKA

According to Annex V of the Directive 93/42/EEC on Medical Devices

93/42/AT Tıbbi Cihaz Yönetmeliği Ek V'e göre

Production Quality Assurance System

Üretim Kalite Güvencesi

Certificate Number: 2195-MED-1732001

Sertifika Numarası

Manufacturer: *Üretici*	**EMSAŞ ELEKTRİK MALZEMELERİ SAN. TİC. A.Ş.** Inönü Mahallesi 28 Sokak Muradiye Köyü Muradiye Bucağı 6 Dış Kapı No Merkez / Manisa TÜRKİYE
Product(s): *Ürün(ler)*	**Product specifications are given on the following page(s).** *Ürün detayları ilerleyen sayfa(lar)da belirtilmiştir.*
Model(s): *Model(ler)*	**Product models are given on the following page(s).** *Ürün modelleri ilerleyen sayfa(lar)da belirtilmiştir.*
Reference Report No: *Referans Rapor No*	MM0648-P004-R01, MM0648-P004-R02

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex V, Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex V, Section 4 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

2195 kimlik numaralı Onaylanmış Kuruluş Szutest, yukarıda belirtilen üreticinin 93/42/AT Tıbbi Cihaz Yönetmeliği EK V bölüm 3'üne göre bir kalite yönetim sistemi uyguladığını, bu yönetim sisteminin yönetmeliğin sadece bahsi geçen ürünün üretiminin güvenlik koşullarını sağlama ve devam ettirme ile ilgili gerekliliklerin karşıladığını beyan eder. Onaylanan bu kalite yönetim sistemi, 93/42/AT Tıbbi Cihaz Yönetmeliği EK V, bölüm 4'e göre periyodik olarak gözetime ve habersiz saha denetimlerine tabidir.

Üretici, ürünlerinin tasarımında ve yapısında gerçekleştirdiği önemli değişiklikleri Szutest'e bildirmek zorundadır. Steril kondisyondaki sınıf I ürünler için kalite yönetim sistemi değerlendirmesi üretimin steril kondisyonun sağlanması ve korunmasıyla limitlidir. Ölçüm fonksiyonlu sınıf I ürünler için Kalite yönetim sistemi değerlendirmesi üretimin cihazların metrolojik şartlara uyumunu sağlamasıyla limitlidir.

This EC certificate is valid till 2024-05-26.

Bu AT Sertifikası 2024-05-26 tarihine kadar geçerlidir.

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. NOTIFIED BODY 2195

Issue Date/*Yayın Tarihi:* 2017-11-16
Revision No./ *Revizyon No.:* 02 Recertification/*Yeniden Belgelendirme*
Revision Date/ *Revizyon Tarihi:* 2020-03-13

Rukiye BALKAN
Deputy General Manager
Genel Müdür Yardımcısı

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

SZUTEST

Certificate Number: 2195-MED-1732001

Sertifika Numarası

Product specifications:
Ürün detayları

(1) Blood Bank Refrigerator *(1) Kan Saklama Dolabı*	EKN 25, EKN 50, EKN100, EKN 200, EKN 300, EKN 600, EKN 25 VK, EKN 50 VK, EKN 100 VK, EKN 200 VK, EKN 300 VK, EKN 600 VK
(2) Trombocyte Incubator *(2) Trombosit İnkübatörü*	ECI-1, ECI-2, ECI-3, ECI-1 VK, ECI-2 VK, ECI-3 VK
(3) Trombocyte Agitator *(3) Trombosit Ajitatörü*	EAJ-05, EAJ-09, EAJ-L09
(4) Blood Plasma Freezer *(4) Plazma Saklama Dolabı*	EE 100, EE 150, EE 300, EE 600, EF 100, EF 150, EF 300, EF 600, EE 100 VK, EE 150 VK, EE 300 VK, EE 600 VK, EF 100 VK, EF 150 VK, EF 300 VK, EF 600 VK

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. NOTIFIED BODY 2195

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
--	-	-	-

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

THE REPUBLIC OF TÜRKİYE
MINISTRY OF HEALTH
MEDICINES AND MEDICAL DEVICES AGENCY OF TÜRKİYE

Certificate No: 374929

Date of Issue : 25 October 2023

CERTIFICATE OF FREE SALE

To whom it may concern,

It is hereby certified that the products detailed in the attached schedule, which are manufactured by "EMSAŞ A.Ş." (*İnönü Mh. 28 Sk. No:6 YUNUSEMRE MANİSA*), have been affixed with the CE mark in accordance with Medical Device Directives of the European Union (EU) and are freely sold in Türkiye and EU.

This certificate is issued to be given to the relevant competent authorities of other countries and is valid for 36 months from the date of issue.

Yours sincerely,

Ömer Faruk KURU
Head of Medical Devices
Registration and Coordination Department

This certificate consists of 4 page/s and 36 products. The products listed in the attached schedule are registered from the date of issuance of this certificate and information about the current status of these products is accessible through

UTS
URUN TAKIP SISTEMI

https://utsuygulama.saglik.gov.tr/UTS/vatandas#/vatTibbiCihazListele.

Address: Sögütözü Mahallesi, 2176. Sokak No:5 06520 Çankaya/ANKARA
Phone: +90 312 218 30 00 Fax: +90 312 218 34 60 https://www.titck.gov.tr

Date of Issue : 25 October 2023

PRODUCT SCHEDULE

#	Barkod	Brand	Label Name	Reference No / Version / Model	GMDN Code
1	8699975060052	EMSAŞ A.Ş.	BLOOD BANK REFRIGERATOR	EKN 25	35486
2	8699975060076	EMSAŞ A.Ş.	BLOOD BANK REFRIGERATOR	EKN 50	35486
3	8699975060090	EMSAŞ A.Ş.	BLOOD BANK REFRIGERATOR	EKN 100	35486
4	8699975060113	Emsaş	BLOOD BANK REFRIGERATOR	EKN 300 VK	35486
5	8699975060137	Emsaş	BLOOD BANK REFRIGERATOR	EKN 600 VK	35486
6	8699975060151	EMSAŞ	PLASMA FREEZERS	EE 300	35704
7	8699975060267	Emsaş	THROMBOCYTE INCUBATOR	ECI-1 VK	62158
8	8699975060281	Emsaş	THROMBOCYTE INCUBATOR	ECI-2 VK	62158
9	8699975060311	EMSAŞ A.Ş.	PLASMA FREEZERS -40	EF150	35704
10	8699975060335	EMSAŞ A.Ş.	PLASMA FREEZERS-40	EF 300	35704
11	8699975060236	Emsaş	PLASMA FREEZERS	EF 600	35704
12	8699975060250	EMSAŞ A.Ş.	THROMBOCYTE AGITATOR	EAJ-L09	45226
13	8699975060243	Emsaş	PLASMA FREEZERS	EF 600 VK	35704
14	8699975060175	Emsaş	PLASMA FREEZERS	EE 600	35704
15	8699975060199	EMSAŞ A.Ş.	THROMBOCYTE INCUBATOR	ECI-02	62158

16	8699975060168	Emsaş	PLASMA FREEZERS	EE 300 VK	35704
17	8699975060182	Emsaş	PLASMA FREEZERS	EE 600 VK	35704
18	8699975060205	Emsaş	PLASMA FREEZERS	EF 150 VK	35704
19	8699975060229	Emsaş	PLASMA FREEZERS	EF 300 VK	35704
20	8699975060298	Emsaş	THROMBOCYTE INCUBATOR	ECI-3	62158
21	8699975060304	Emsaş	THROMBOCYTE INCUBATOR	ECI-3 VK	62158
22	8699975060144	EMSAŞ	PLASMA FREEZERS	EE 150VK	35704
23	8699975060069	Emsaş	BLOOD BANK REFRIGERATOR	EKN 25 VK	35486
24	8699975060083	Emsaş	BLOOD BANK REFRIGERATOR	EKN 50 VK	35486
25	8699975060045	Emsaş	BLOOD BANK REFRIGERATOR	EKN 100 VK	35486
26	8699975060021	Emsaş	BLOOD BANK REFRIGERATOR	EKN 200 VK	35486
27	8699975060342	EMSAŞ	PLASMA FREEZERS	EE 100	35704
28	8699975060366	EMSAŞ	PLASMA FREEZERS	EF 100	35704
29	8699975060038	EMSAŞ	BLOOD BANK REFRIGERATOR	EKN 300	35486
30	8699975060120	EMSAŞ	BLOOD BANK REFRIGERATOR	EKN 600	35486
31	8699975060359	EMSAŞ	PLASMA FREEZERS	EE 100VK	35704
32	8699975060328	EMSAŞ	THROMBOCYTE AGITATOR	EAJ 09	45226
33	8699975060373	EMSAŞ	PLASMA FREEZERS	EF 100VK	35704
34	8699975060397	EMSAŞ	BLOOD BANK REFRIGERATOR	EKN 200	35486

35	8699975060274	EMSAŞ	THROMBOCYTE AGITATOR	EAJ 05	45226
36	8699975060410	EMSAŞ	THROMBOCYTE INCUBATOR	ECI 1	62158

End of product schedule