

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



Depuby 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>.

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE

Szutest.com.tr



CERTIFICATE

EMSAŞ ELEKTRİK MALZEMELERİ SANAYİ VE TİCARET ANONİM ŞİRKETİ MANİSA ŞUBESİ

MURADIYE SANAYİ BÖLGESİ MURADIYE 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



IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.

Beşevler Mah. Kocayunus Sk. No:3 Arslan Han Plaza K:2 Nilüfer / BURSA

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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



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

Address: Söğütözü 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>

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



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

End of product schedule

