

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



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 reissued.



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



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



EC Declaration of Conformity

Manufacturer's Name: EMSAŞ ELEKTRİK MALZEMELERİ SAN. VE TİC. A.Ş.

Manufacturer's Address: Muradiye Mahallesi 28 Sokak Dış Kapı No:6 Yunusemre / Manisa / TÜRKİYE

Declares in sole responsibility that the CE certified product.

Equipments: Medical Devices, Refrigerators, Warming Cabinets and Plasma Thawers

Product Models and Description

Pharmacy Refrigerator ; EKT80 , EKT150 , EKT160 , EKT175 , EKT250 , EKT 425 , EKT 725 , EKT2x725, EKT1450 , EKT-A 80 , EKT-A 100 , EKT-A 175 , EKT-A-250 , EKT-A 425 , EKT-A 725 , EKT-A 1450 ,

Refrigerator EK380 , EKL380

Portable Refrigerator & Freezer

Ultra Low Freezers ; ULT100, ULT200, ULT470 , ULT730 , ULT800 , YULT350

Breast Milk Cooling Cabinet and Freezers ; ANS-F 150 , ANS-E-175 , ANS-D-425 ,

Baby Bottle Warmers; EBI06 , EBI09 , EBI12 , EBI24

Combined Refrigerator and Freezer; EKT-D 175 , EKT-D 425 , EKT-D 500 ,

Fluid and Blanket Warming Cabinet; EMI-50 ,EMI-80, EMI-150 , EMI-250, EMI-350 , EMI-500 , EMI-D-500 ,

Plasma Thawer; EPS10 – EPT6

Circulating Water bath ; ESB10

Drying and Heating Oven; ET150 , ET60

Cooled Incubator; ESI100

Above mentioned commodity is consistent to the below mentioned standards.01/01/2019

EN 60601-1 Medical Electrical Equipment

60601-1-2

61010-1

61326-1

Directives:

93/42/EC Medical Devices

93/68/EEC CE Marking Directive

2017/745

This is to certify that the product and current types described above is in conformity with the applicable requirements of the directive.

Conformity assesment procedure; 93/42/EEC Medical Devices Class I , 2017/745

Signed by Name - Position: Sinem TURKOGLU – Vice Chairman of Management Board

Signature


EMSAŞ
ELEKTRİK MALZEMELERİ SAN. TİC. A.Ş.
1214 Sok.No:16 Naldöken-Bornova
Tel:0 212 479 54 22 Fax:479 74 11 ZMİR
Bornova V.D.334 009 5711

Date / Place 02.01.2025 – Manisa / Turkey