



EC Declaration of Conformity

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

Manufacturer's Address: 1214 street No:16 NALDOKEN-BORNOVA/İZMİR/TURKEY

Declares in sole responsibility that the CE certified product.

Equipments: Medical Refrigerators , Warming Cabinets and Plasma Thawers

Product Models and Description

Vaccine and Drug Storage Cooling Cabinets; EKT80 , EKT150 , EKT160 , EKT175 , EKT250 , EKT 425 , EKT 725 , EKT 2x725, EKT1450 , EKT-A 80 , EKT-A 100 , EKT-A 175 , EKT-A-250 , EKT-A 425 , EKT-A 725 , EKT-A 1450 , EK372.

Plasma Freezers; EE100 , EE150 , EE300 , EE600 , EF100 , EF150 , EF300 , EF600 ,

Ultra Low Freezers ; ULT200, ULT470 , ULT730 , YULT400

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

Baby Bottle Warmers; EBI6 , EBI12 , EBI24 , EBI36

Vaccine and Drug Storage Cooling Cabinets with Freezer Section; EKT-D 175 , EKT-D 425 , EKT-D 500 ,

Serum and Blanket Warming Cabinet; EMI-50 , EMI-150 , EMI-350 , EMI-D-500 ,

Plasma Thawer; EPS10

Circulating Water bath ; ESB10

Drying and Heating Oven; ET150

Cooled Incubator; ESI100

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

EN 60601-1 Medical Electrical Equipment

Directives:

93/42/EC Medical Devices

93/68/EEC CE Marking Directive

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/EC Medical Devices Class I Non Steril

Signed by Name - Position: Sinem VARDAR -Company Executive

Signature


EMSAŞ ELEKTRİK MALZEMELERİ SAN. VE TİC. A.Ş.
1214 Sok. No: 16 Naldoken-Bornova
İzmir 35210
Tic. Sic. No: 270907
V.D. 334 009 5711

Date / Place 01.01.2020 – Manisa / Turkey



TO WHOM IT MAY CONCERN

CLARIFICATION LETTER

The medical devices classified as Class II, have notified body CE Certificate issued by third party. These devices are;

- Blood Bank Refrigerator: EKN25 , EKN50, EKN100, EKN200, EKN300, EKN600, EKN25 VK , EKN50 VK, EKN100 VK, EKN200 VK, EKN300 VK, EKN600 VK
- Thrombocyte Incubator: ECI-1, ECI-2, ECI-2, ECI-1 VK, ECI-2 VK, ECI-3 VK
- Thrombocyte Agitator: EAJ05, EAJ09, EAJ-L09
- Blood Plasma Freezer: EE100, EE150, EE300, EE600, EF100, EF150, EF300, EF600, EE100 VK, EE150 VK, EE300 VK, EE600 VK, EF100 VK, EF150 VK, EF300 VK, EF600 VK

Attachment 1; CE certificate issued by SZUTEST

However, the Laboratory Refrigerators classified as Class I, have only CE declaration of conformity issued by manufacturer, Class I Devices cannot have the CE Certificate approved by third parties. These devices are;

- Ultra Low Freezer: YULT300 , ULT200 , ULT470 , ULT730
- Laboratory & Pharmacy Refrigerator: EKT80, EKT-A80, EKT150, EKT-A100 , EKT175, EKT-A175, EKT425 , EKT-A425, EKT725 , EKT-A725, EKT 1450 , EKT-A 1450, EK372
- Refrigerator with Two Section: Fridge + Freezer: EKT-D 175, EKT-D 425, EKT-D 500.
- Etuve (Laboratory Drying and Heating Oven): ET150
- Water Bath : ESB10

Attachment 2; CE Declaration of Conformity issued by Manufacturer EMSAS A.S.

EMSAS ELEKTRİK MALZEMELERİ SANAYİ VE TİCARET A.Ş.


ELEKTRİK MALZEMELERİ SAN. TİC. A.Ş.
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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
Refrigerator, 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



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>.

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

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

Szutest.com.tr

Our laboratory freezers are produced with 3 different capacity option.

- The outer surface of the device is made of galvanized steel, painted with electrostatic paint to protect against rust. The inner surface is produced of stainless steel.
- The device operates with 195-230 V/50 Hz network voltage.
- The door of the device comes with a high density polyurethane filling insulation, which has a heating surface and magnetic seal rings to provide impermeability.
- The inner shelf system has been produced of stainless steel material. It has been designed ergonomically for speeding up the air circulation.
- The deep freezer provides the opportunity to store between -20°C /-40°C.
- The insulation of the deep freezer is provided with a high density of polyurethane material.
- The device works smooth and quietly.
- The lightening of the inner cabin of the device is carried out with LED lights.
- The user-friendly digital control panel, which carried out with a micro processor, enables to keep the data in memory for 30 days.
- There is a USB socket to transfer the cabinet temperature information to the computer when requested. In this way, the 10 year old temperature records can be transferred to the PC in excel format.
- There is an accumulator system charged automatically at the control panel of the device. This system allows the control panel and thermal printer (if available) to operate for 24 hours when the electricity cuts off.
- The freezer alerts you with visual and audio signals when the lower and upper temperature limits are exceeded, the door of the device is left open, low voltage and/or electricity cut off problems occurs.
- The refrigerant and the insulation of the deep freezer do not contain CFC gas which is harmful for the OZONE.
- There are two braked and two regular castors on the device that provide easy portability.
- As per request of the user, a thermal printer can be installed at the device. The numerical printout of the recorded data can be taken with the thermal printer.
- All medical devices produced by Emsaş A.Ş. are guaranteed for 2 years.

- All our products are produced in line with the ISO 9001:2008, TSE service place competence certificates.

Our deep freezers have CE certificates.