Digitally signed by Bolea Petru
Date: 2024.08.22 17:32:09 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

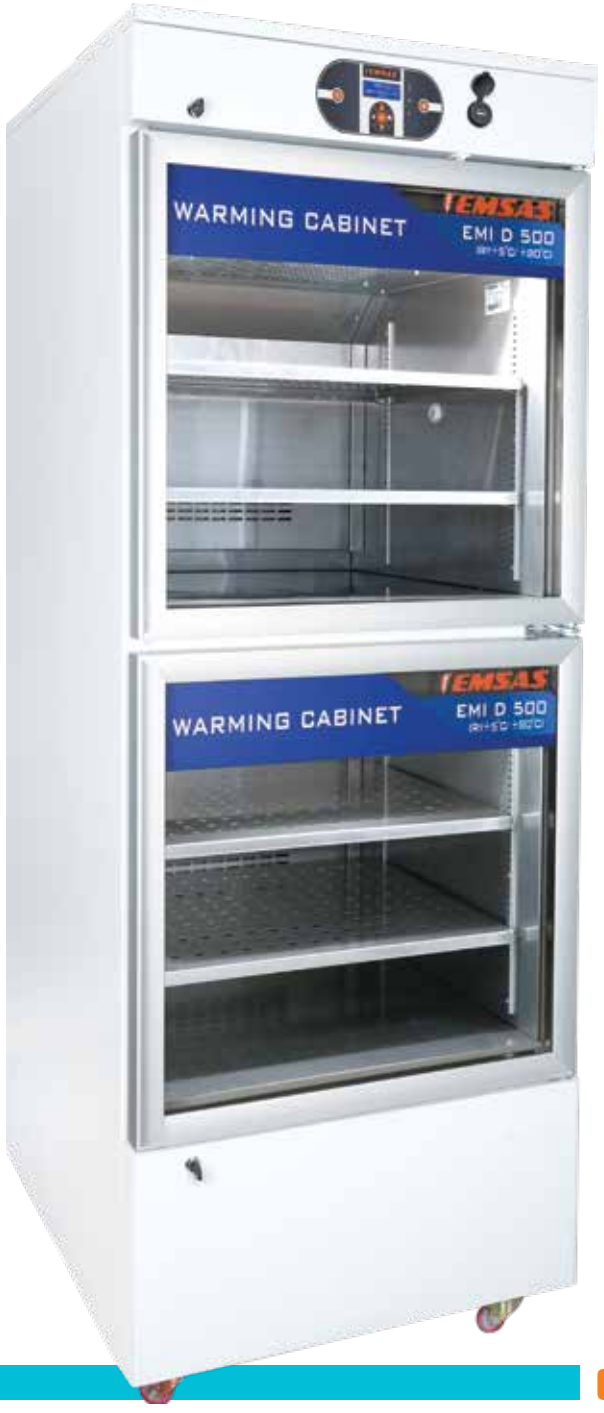
EMSAS®

MEDICAL COOLING & HEATING SYSTEMS

www.emsas-as.com.tr

EMI Serie
(Rt+5 °C / +80 °C)

EMI-D 500
(RT+5°C /+80°C)



• The outer surface of the device has been produced of galvanized sheet with electrostatic paint resistant to rust and the inner surface is produced of chrome nickel sheet. Works with 220V/50 Hz mains voltage.

• Temperature change ability with password.

• Cabinet's door is double coated heat glassed, lockable ad magnetic sealed which allows stocktaking.

• There are plastic covered wire shelves which can be adjusted according to the user's request.

• The cabinet has over-temperature protection as electronic up to 80 degrees, mechanically up to 90 degrees.

• Equal heat distribution is provided by the reinforced fan system in the cabinet.

• There is a filter in the device to prevent the possibility of an external contamination to the air circulation system.

• A fully automatic defrost system is available to maintain the efficiency of the cupboard cooling evaporator.

• Cabinet interior lighting is realized with led lighting.

• A user friendly microprocessor digital control panel is used on the cabinet. This system can store the data for 30 days in the memory and the old records can be followed on the screen.

• 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.

• The thermostat in the cabinet control panel can measure with 0.1 degree accuracy.

• Sensor adjustment can be done via electronic card to match external sensor and cabinet grades.

• 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 cutts off.

• When the upper and lower temperature limits are exceeded while the cup board was working, while the door is open, the appliance gives a visual and audible warning signal when an electrical interruption occurs.

• Warming time: 3-7 hours

• As per the request of the user, a thermal printer can be installed at the device. The numerical print out.

of the data recorded with the thermal printer can be taken.

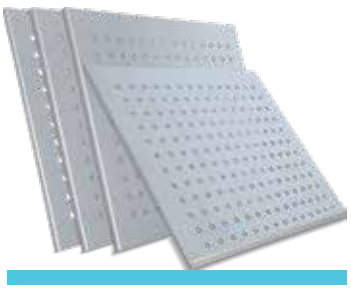
• All medical devices produced by Emsaş A.Ş. are guaranteed for 2 years.

• All our products are produced in line with the ISO 9001:2008, TSE service place competence certificates. The device has CE certificates and barcode.

EMI-D 500

OPTIONAL THERMAL PRINTER

OPTIONAL TOUCH SCREEN DISPLAY



STANDARD CHROME SHELVES

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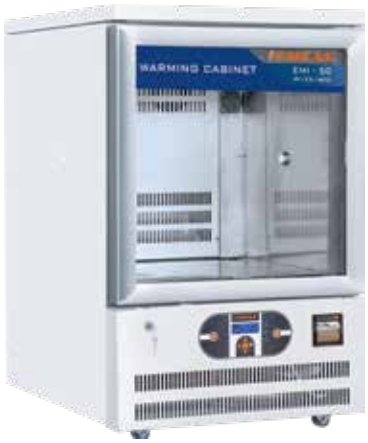
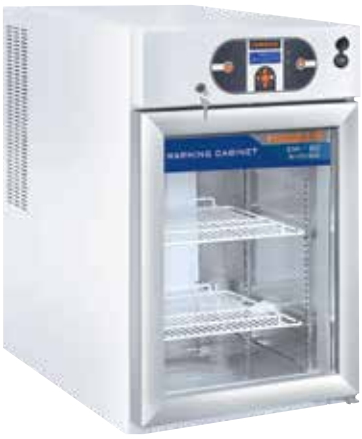
EMI 50 (Rt+5°C/+80°C)

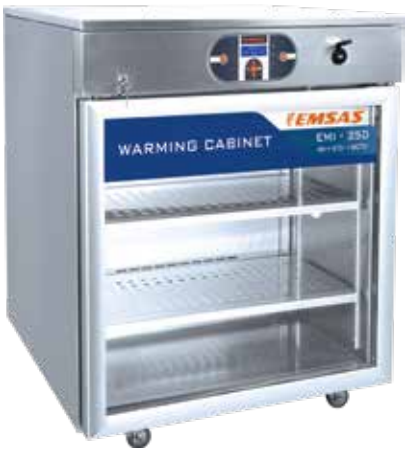


EMI 80 (Rt+5°C/+80°C)

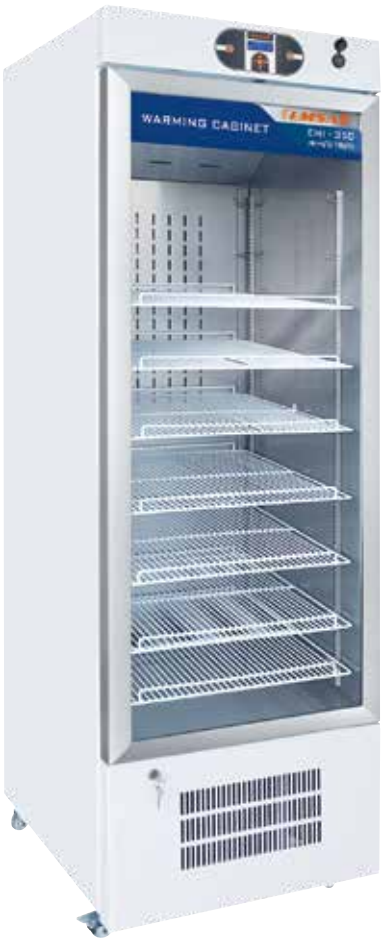


EMI 150 (Rt+5°C/+80°C)

EMI 250 (Chrome) (Rt+5°C/+80°C)



EMI 350 (Rt+5°C/+80°C)



MODEL	EMI 50	EMI 80	EMI 150	EMI 250	EMI 350	EMI-D 500
Temperature Range	Rt+5°c / +80°c	Rt+5°c / +80°c	Rt+5°c / +80°c	Rt+5°c / +80°c	Rt+5°c / +80°c	Rt+5°c / +80°c
Set Point	+50°c	+50°c	+50°c	+50°c	+50°c	+50°c
External Dimensions (WxLxH) mm	600x695x910	452x653x752	600x660x1446	765x823x900	600x660x2040	765x825x2020
Internal Dimensions (WxLxH) mm	496x455x496	368x365x420	516x472x797	660x360x900	515x472x1390	666x652x536
Volume	140 L	100 L	225 L	250 L	388 L	295 L * 2 (for 2 cabinet)
Polyurethane (mm)	52 mm	50 mm	42,5 mm	42,5 mm	42,5 mm	50 mm
Packaged Dimensions (WxLxH)mm	680x740x1050x	630x700x950x	680x740x1540	870x930x1030	670x710x2150	850x900x2100
Gross KG	85 Kg	50 Kg	107 Kg	105 Kg	120 Kg	150 Kg
Interior Lightening	+	+	+	+	+	+
Door Lock	+	+	+	+	+	+
Alarm	+	+	+	+	+	+
Internal Surface	Stainless Steel Cr-Ni 304	Stainless Steel Cr-Ni 304	Stainless Steel Cr-Ni 304	Stainless Steel Cr-Ni 304	Stainless Steel Cr-Ni 304	Stainless Steel Cr-Ni 304
External Surface	Galvanized sheet with electrostatic paint Optional / Stainless Steel Cr-Ni 304	Galvanized sheet with electrostatic paint Optional / Stainless Steel Cr-Ni 304	Galvanized sheet with electrostatic paint Optional / Stainless Steel Cr-Ni 304	Chrome	Galvanized sheet with electrostatic paint Optional / Stainless Steel Cr-Ni 304	Galvanized sheet with electrostatic paint Optional / Stainless Steel Cr-Ni 304
Heating / Cooling System	Fan System	Fan System	Fan System	Fan System	Fan System	Fan System
Insulation	CFC Free - Polyurathane	CFC Free - Polyurathane	CFC Free - Polyurathane	CFC Free - Polyurathane	CFC Free - Polyurathane	CFC Free - Polyurathane
Shelves	1 Pcs	1 Pcs	3 Pcs	2 Pcs	5 Pcs	2 Pcs / 2 Pcs
Chrome Shelves	Standard	Standard	Standard	Standard	Standard	Standard
Thermal Printer	Optional	Optional	Optional	Optional	Optional	Optional
SMS and E-MAIL MODULE	Optional	Optional	Optional	Optional	Optional	Optional
PC Connection	USB	USB	USB	USB	USB	USB
Castor	2 Braked , 2 Regular	2 Braked , 2 Regular	2 Braked , 2 Regular	2 Braked , 2 Regular	2 Braked , 2 Regular	2 Braked , 2 Regular
Temperature Sensor	NTC	NTC	NTC	NTC	NTC	NTC
Control System	PID	PID	PID	PID	PID	PID
Voltage	220v-50hz	220v-50hz	220v-50hz	220v-50hz	220v-50hz	220v-50hz / 220v-50hz
Power	450 Watt	450 Watt	450 Watt	450 Watt	450 Watt	900 Watt

sinoions © 2022-10

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MEDICAL COOLING & HEATING SYSTEMS

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ISO 9001:2008
ISO 13485
CE

Muradiye Sanayi Bölgesi Muradiye Mahallesi
28 Sokak No:6 Yunusemre - MANiSA / TURKEY
Tel: +90 (236) **214 03 96 - 97 - 98** Fax: +90 (236) **214 07 06**
izmir Tel: +90 (232) **479 55 22 - 479 55 23**
mail: export1@emsas-as.com.tr
www.emsas-as.com.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: 21/05/2024 14:58:26

NB 0476

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
-	-	-	-

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
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

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/16	Rev.00	Initial issue

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

EC Declaration of Conformity

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

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

Declares in sole responsibility that the CE certified product.

Equipmens: 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 , EKT1450 , EKT-A 80 , EKT-A 100 , EKT-A 175 , EKT-A-250 , EKT-A 425 , EKT-A 725 , EKT-A 1450 , EK372 , EK-A 372 , EKM B 372

Back Bar Cooler ; EBB200

Ultra Low Freezers ; ULT470 , ULT730 , YULT300

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

Baby Bottle Warmers; EBI06 , EBI08 , EBI12 , EBI24 , EBI36

Vaccine and Drug Storage Cooling Cabinets with Freezer Section; 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

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 confirmity 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.TİC.A.Ş.
1214 Sok.No:16 Naldöken-Bornova
Tel:0.232 479 54 22 93 Fax:479 74 11-İZMİR
Bornova V.D.334 005 5711

Date / Place 01.01.2020 – Manisa / Turkey

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

This version of certificate has come into force on 28.03.2017. Bu sertifika versiyonu 28.03.2017 tarihinde yürürlüğe girmiştir. TR 2195-MED-1732001 Rev.02

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

This version of certificate has come into force on 21/02/2017 / Bu sertifika versiyonu 21/02/2017 tarihinde yürürlüğe girmiştir. 2/2 2195-MED-1732001 Rev.02

TO WHOM IT MAY CONCERN

CLARIFICATION LETTER

It is classified as Pharmacy Refrigerator Class I according to EU regulations and FDA regulations in the world. Blood Bank Refrigerator, Freezer , Incubator and Agitator etc. are classified as Class II.

The below 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 below medical devices 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;

-Laboratory & Pharmacy Refrigerator: EKT80, EKT-B80, EKT150, EKT-B150 , EKT175, EKT-B 175, EKT250 , EKT-B250, EKT425 , EKT-B 425, EKT725 , EKT-B 725, EKT 1450 , EKT-B 1450, EK372, EK372 with Memory

-Two Sections Combined: Pharmacy+Freezer Refrigerator : EKT-D 175 , EKT-D 425 , EKT-D 500

-Ultra Low Freezer : YULT300 , ULT200 , ULT470 , ULT730

-Breast Milk Refrigerators and Freezers: ANS-E175 , ANS-F 150 ,ANS-D 425

-Baby Bottle Warmer: EBI06 , EBI09, EBI12 , EBI24 - Water Bath : ESB10

-Etuve (Laboratory Drying and Heating Oven): ET150

- Plasma Thawer : EPS10

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

EMSAS ELEKTRIK MALZEMELERI SANAYI VE TICARET A.S.

Muradiye Sanayi Bölgesi Muradiye Mahallesi 28 Sokak No:6 Yunusemre – MANİSA / TURKEY
Tel: +90 (236) 214 03 96 -97 -98 Fax: +90 (236) 214 07 06
export1@emsas-as.com.tr www.emsas-as.com.tr

SZUTEST

CERTIFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 32104001

EMSAŞ ELEKTRİK MALZ. SAN. TiC. 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.

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

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*	: 10.09.2023
Geçerlilik Periyodu	/ *Period of Registration*	: 3 Yıl / *Years*
Geçerlilik Tarihi	/ *Date Certificate Expires*	: 09.09.2024
Sertifika Numarası	/ *Certificate No*	: 01/11240/09

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

TÜRKAK BDS NO
YS-BC5C-C791

Onay:
Approved by:

SERTİFİKASYON ★ CERTIFICATION ★ ZERTİFİZİERUNG ★ СЕРТИФИКАЦИЯ ★
ASB

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.

ASB Uluslararası Belgelendirme Gözetim Denetim ve Eğitim Hiz. Ltd. Şti. / *ASB International Certification Surveillance, Auditing and Training Services Ltd. Company*
Tatlısu Mh. Akif İnan Sk. Sevim Residence No:16 Daire:13 Kat:06 Ümraniye – İstanbul / TÜRKİYE Tel: +90 216 526 10 04 Fax: +90 216 526 30 91 e-mail: bilgi@asbcert.com.tr
Bu sertifika, kuruluşun ASB'nin şartlarına uyduğu sürece geçerlidir. Sertifikanın durumu www.asbcert.com.tr adresinden kontrol edilebilir.
The Validity shall remain in force as long as the corporation follows instructions of ASB. Certificates status can be checked at www.asbcert.com.tr

CE AB UYGUNLUK BEYANI/DECLARATION OF CONFORMITY

ÜRETİCİ/PRODUCER :EMSAŞ ELEKTİK MALZEMELERİ SANAYİ VE TİCARET A.Ş

ADRES/ADDRESS :28SK NO:6 YUNUSEMRE MURADİYE MANİSA/Türkiye

TELEFON/PHONE :00902362149697-98

E-MAIL : ***info@emsas-as.com.tr***

WEB-SİTESİ: ***:www.emsas-as.com.tr***

MARKA/BRAND**:EMSAŞ**

ÜRÜNLER/PRODUCTS	**SERUM ISITMA CİHAZI / FLUID WARMING CABINET**
ÜRÜN KODU/PRODUCT CODE	**EMI50/EMI150/EMI250/EMI350/EMI-D-500/EMI500**
SINIFI /CLASS	**:SINIF 1 , CLASS I**
DİREKTİF /DIRECTIVE	2017/745 MDR Ek-IV
BASIC UDI	**869997506EMI35**

THIS DECLARATION CONFORMITY ISSUED BY ONLY THE RESPONSIBILITY OF THE PRODUCER. WE DECLARE THAT; FOLLOWING MEDICAL DEVICE/S ARE MET TO MDR 2017/745 (EU) PROVISION FOR MEDICAL DEVICES.

BU UYGUNLUK BEYANI, YALNIZCA [ÜRETİCİ] 'NİN SORUMLULUĞU ALTINDA DÜZENLENMİŞTİR. YUKARIDA BELİRTİLEN TIBBI CİHAZIN/CİHAZLARIN TIBBİ CİHAZLAR İÇİN YÖNETMELİK (AB) MDR 2017/745 HÜKMÜNÜ KARŞILADIĞINI BEYAN EDERİZ..

GEN.MD.YRD / VICE OF GENERAL MANAGER
SIGNATURE: SINEM VARDAR

CITY,:MANISA/TURKEY
DATE: 01.01.2022

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

Certificate No: 374909

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 2 page/s and 4 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

Basic UDI-DI: 869997506EMI3S

Related EU Certificate(s) (if any): - ; -

#	UDI-DI	Brand	Label Name	Reference No / Version / Model	GMDN Code
1	8699975060427	EMSAŞ	FLUID AND BLANKET WARMERS	EMI150	38469
2	8699975060434	EMSAŞ	FLUID AND BLANKET WARMERS	EMI350	38469
3	8699975060441	EMSAŞ	FLUID AND BLANKET WARMERS	EMI-D 500	38469
4	86999750611164	EMSAŞ	FLUID AND BLANKET WARMERS	EMI 100	38469

End of product schedule

SZUTEST

Kimden/From : Hasan Akkök

E-Posta/E-Mail : hasan.akkok@szutest.com.tr

Szutest Uygunluk Değerlendirme Anonim Şirketi
Tatlısu Mahallesi Akif İnan Sokak No:1/1
Ümraniye-İstanbul, Turkey
Tel: 00 90 216 469 46 66
Fax: 00 90 216 469 46 67
www.szutest.com

EMSAŞ ELEKTRİK MALZ. SAN. TiC. A.Ş.

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

Ref. :

Tarih/Date : 17.05.2024

Konu/Subject : 93/42/EEC Annual Surveillance Audit

To whom it may concern,

The annual surveillance audit responsibility for the company's 93/42/EEC certificates, as detailed below, will be applicable under the following circumstances. If the company does not apply to an authorized notified body within the scope of (EU) 2017/745, the responsibility extends until the certificate's validity date. However, if the company applies to an authorized notified body within the scope of (EU) 2017/745 by 26.05.2024 and signs a contract by 26.09.2024, in accordance with (EU) 2017/745, the annual surveillance audits, as per the provisions of paragraph 3e of Article 1 of Regulation (EU) 2023/607, will be conducted by SZUTEST Uygunluk Değerlendirme A.Ş. until 26.09.2024.

Company Name: EMSAŞ ELEKTRİK MALZ. SAN. TiC. A.Ş.
Products:
(1) Blood Bank Refrigerator
Certificate #1; 2195-MED-1732001
Issue Date:16.11.2017
Expiry Date: 26.05.2024

(2) Trombocyte Incubator
Certificate #1; 2195-MED-1732001
Issue Date:16.11.2017
Expiry Date: 26.05.2024

(3) Trombocyte Agitator
Certificate #1; 2195-MED-1732001
Issue Date:16.11.2017
Expiry Date: 26.05.2024

(4) Blood Plasma Freezer
Certificate #1; 2195-MED-1732001
Issue Date:16.11.2017
Expiry Date: 26.05.2024

I here submit for your information.
Best Regards.

SZUTEST
UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mah. Akif İnan Sk. No:1/1
Ümraniye / İSTANBUL
Alemdağ V.D.: 7880487774

Hasan Akkök
Competent Authority and Committee Coordinator

SZUTEST

Kimden/From : Hasan Akkök

E-Posta/E-Mail : hasan.akkok@szutest.com.tr

Szutest Uygunluk Değerlendirme Anonim Şirketi
Tatlısu Mahallesi Akif İnan Sokak No:1/1
Ümraniye-İstanbul, Turkey
Tel: 00 90 216 469 46 66
Fax: 00 90 216 469 46 67
www.szutest.com

EMSAŞ ELEKTRİK MALZ. SAN. TiC. A.Ş.

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

Ref. :

Tarih/Date : 17.05.2024

Konu/Subject : 93/42/EEC Gözetim Denetimi Hk.

İlgili makama,

Aşağıda bilgileri yer alan firmanın 93/42/EEC sertifikalarına ait yıllık gözetim denetimi sorumluluğu, firmanın (EU) 2017/745 kapsamında yetkili bir onaylanmış kuruluşa başvurmaması durumunda sertifika geçerlilik tarihine kadar, 26.05.2024 tarihine kadar (EU) 2017/745 kapsamında yetkili bir onaylanmış kuruluşa başvurması ve 26.09.2024 tarihine kadar (EU) 2017/745 kapsamında yetkili bir onaylanmış kuruluşla sözleşme imzalaması durumunda (EU) 2023/607 yönetmeliği 1. maddesinin 3e paragrafı kapsamında 26.09.2024 tarihine kadar SZUTEST Uygunluk Değerlendirme A.Ş. tarafından yürütülecektir.

Firma Adı: EMSAŞ ELEKTRİK MALZ. SAN. TiC. A.Ş.
Ürünler:
(1) Kan Saklama Dolabı
Sertifika #1: 2195-MED-1732001
Yayın Tarihi: 16.11.2017
Geçerlilik Tarihi:26.05.2024

(2) Trombosit İnkübatörü
Sertifika #1: 2195-MED-1732001
Yayın Tarihi: 16.11.2017
Geçerlilik Tarihi:26.05.2024

(3) Trombosit Ajitatörü
Sertifika #1: 2195-MED-1732001
Yayın Tarihi: 16.11.2017
Geçerlilik Tarihi:26.05.2024

(4) Plazma Saklama Dolabı
Sertifika #1: 2195-MED-1732001
Yayın Tarihi: 16.11.2017
Geçerlilik Tarihi:26.05.2024

Bilginize arz ederim.
Saygılarımla.

SZUTEST
UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mah. Akif İnan Sk. No:1/1
Ümraniye / İSTANBUL
Alemdağ V.D.: 7880487774

Hasan Akkök
Yetkili Otorite İletişim ve Komite Koordinatörü