2021

CERTIFICATE OF REGISTRATION

This certifies that:

EMSAS ELEKTIRIK MALZEMELERI SAN. VE TICARET A.S.

1214 SOKAK NO:16 35000 IZMIR TURKEY

is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Bioterrorism Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as currently effective on the date hereof by Royal Ace Foods Inc.:

U.S. FDA Registration No.: **14490050824**

U.S. Agent for FDA **ROYAL ACE FOODS INC.**

Communications: **4590 Qantas Ln, Suıte A7 Stocton CA 95206 USA**

This certificate affirms that above stated facility is registered with the US. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Bioterrorism Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as effective by Royal Ace Foods INC., as of the date hereof, and Royal Ace Foods INC. Will confirm that such registration remains effective upon request and presentation of this certificate until December 31,2021, unless such registration has been terminated after issuance of this certificate. Royal Ace Fodds INC. Makes no other representations or warranties, nor does this certificate make any representations or waranties to any person or entity other than the named certificate holder , for whose sole benefit it is issued. Royal Ace Foods INC. assumes no liability to any person or entity in connection with the foregoing. The US. Food and Drug Administration does not issue a certificate of registration, nor does the US. Food and Drug Administration recognize a certificate of registration. Royal Ace Foods INC. is not affiliated with.the US food and Drug Administration.

PGM
Proje Gözetim Mühendislik
Project Inspection Engineering

Alemdag cad. Kısıklı Mah. No 60 Masaldan

Is Merkezi B Blok Kat 4 Istanbul TURKEY

FDA

THE REPUBLIC OF TURKEY
MINISTRY OF HEALTH
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY

Certificate No: 103133

Date of Issue : 30 October 2020

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 Turkey.

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.

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.

Yours sincerely,

Asım HOCAOĞLU, Ph.D.
Head of Medical Devices
Registration and Coordination Department

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 : 30 October 2020

PRODUCT SCHEDULE

#	Barcode	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 FREEZER	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 FREEZER	EF150	35704
10	8699975060335	EMSAŞ A.Ş.	PLASMA FREEZER	EF 300	35704
11	8699975060236	Emsaş	PLASMA FREEZER	EF 600	35704
12	8699975060250	EMSAŞ A.Ş.	THROMBOCYTE AGITATOR	EAJ-L09	45226
13	8699975060243	Emsaş	PLASMA FREEZER	EF 600 VK	35704
14	8699975060175	Emsaş	PLASMA FREEZER	EE 600	35704

Asım HOCAOĞLU, Ph.D.
Head of Medical Devices
Registration and Coordination Department

15	8699975060199	EMSAŞ A.Ş.	THROMBOCYTE INCUBATOR	ECI-02	62158
16	8699975060168	Emsaş	PLASMA FREEZER	EE 300 VK	35704
17	8699975060182	Emsaş	PLASMA FREEZER	EE 600 VK	35704
18	8699975060205	Emsaş	PLASMA FREEZER	EF 150 VK	35704
19	8699975060229	Emsaş	PLASMA FREEZER	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 FREEZER	EE 150	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 FREEZER	EE 100	35704
28	8699975060366	EMSAŞ	PLASMA FREEZER	EF 100	35704

End of product schedule.

Asim HOCAOGLU, Ph.D.
Head of Medical Devices
Registration and Coordination Department

THE REPUBLIC OF TURKEY
MINISTRY OF HEALTH
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY

Certificate No: 171377

Date of Issue : 5 November 2021

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 Turkey.

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 8 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.

UTS
ÜRÜN TAKİP SİSTEMİ

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 : 5 November 2021

PRODUCT SCHEDULE

#	Barkod	Brand	Label Name	Reference No / Version / Model	GMDN Code
1	8699975060038	EMSAŞ	Bood Bank Refrigerator	EKN 300	35486
2	8699975060120	EMSAŞ	Bood Bank Refrigerator	EKN 600	35486
3	8699975060359	EMSAŞ	Plasma Rreezer	EE 100VK	35704
4	8699975060328	EMSAŞ	Platelet Thrombocyte Agitator	EAJ 09	45226
5	8699975060373	EMSAŞ	Plasma Rreezer	EF 100VK	35704
6	8699975060397	EMSAŞ	Bood Bank Refrigerator	EKN 200	35486
7	8699975060274	EMSAŞ	Platelet Thrombocyte Agitator	EAJ 05	45226
8	8699975060410	EMSAŞ	Incubator	ECI 1	62158

End of product schedule.

Product list to Free Sales Certificate no. 171377

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.

Issue Date	09.02.2021
Expiry Date	08.02.2024

TÜRKAK BDS NO
YS-9AA4-4E58

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.

SERTİFİKA

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

EA 17, 18 kapsamında
at scope EA 17, 18

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*	: 12.09.2021
Geçerlilik Periyodu	/ *Period of Registration*	: 3 Yıl / *Years*
Geçerlilik Tarihi	/ *Date Certificate Expires*	: 11.09.2022
Sertifika Numarası	/ *Certificate No*	: 01/11240/07

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

TÜRKAK BDS NO
YS-31DD-DC9E

Onay:
Approved by:

SERTİFİKASYON ★ CERTIFICATION ★ ZERTIFIZIERUNG ★ 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

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

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 , EKT 2x725, EKT1450 , EKT-A 80 , EKT-A 100 , EKT-A 175 , EKT-A-250 , EKT-A 425 , EKT-A 725 , EKT-A 1450 ,EKC372.

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

Ultra Low Freezers ; ULT200, ULT470 , ULT730 , YULT300

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 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 Fax:479 74 11-İZMİR
Bornova V.D.334 005 5711

Date / Place 01.01.2020 – Manisa / Turkey

DECLARATION of CONFORMITY

MANUFACTURER : *EMSAŞ ELEKTRİK MALZEMELERİ SAN. TİC. A.Ş.*

ADRESS : *Muradiye Sanayi Bölgesi 28 Sokak No: 6 Yunusemre / MANISA /TURKIYE*

PHONE : *+90 236 214 03 96 – 97 - 98*

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

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

We declare that following product are in accordance with ***93/42/EEC Medical Device Directive (and 2007/47/EC amendment) ANNEX V, 2006/42/EC Machinery Directive, 2014/30/EU Electromagnetic Compatibility Directive*** *and* ***applicable standards.***

PRODUCT NAME : *EE 150 , EE 300 , EF 150 , EF300 Plasma Freezer*
EKN 25 , EKN 50 , EKN 100 , EKN 200 ,EKN300 , EKN600 Blood Bank Refrigerator
ECI1 , ECI2 , ECI3 Incubator , EAJ05 , EAJ09 , EAJL09 Agitator ,
EPS10 Plazma Thawer,EMI50 , EMI150 , EMI350,EMI-D 500 Warming Cabinet

CLASS : *IIa*

RULE : *2 (According to Annex IX, 93/42/EEC)*

APPLICABLE STANDARDS:

TS EN 980:2008	TS EN ISO 15223-1:2016
TS EN ISO 14971:2016	TS EN 1041:2014
TS EN 62366:2016	TS EN 62366-1:2016
TS EN 61010 -1:2012	TS EN 60027-1:2010
TS EN 60601-1,	TS IEC 60601-1
TS IEC 60227-6:2003	TS IEC 60245-7:2007
TS EN 61326-1:2013	TS EN 61000-4-2:2014
TS EN 61000-4-4:2013	TS EN 61000-4-5:2014
TS EN 61000-4-6:2014	TS EN 61000-4-8:2010
TS EN 61000-4-11:2006	TS EN ISO 10993 – 1:2014

GMDN NR.: *35704- Freezer, blood product*

NOTIFIED BODY: *SZUTEST Teknik Kontrol ve Belgelendirme Hizmetleri Tic. Ltd. Şti. ,Yukarı dudullu Mah. NATO Yolu Cad. Çam Sokak No: 7 Ümraniye – İSTANBUL*

EC CERTIFICATE NO: : *2195-MED-1732001*

EC CERTIFICATE DATE: : *16.11.2017*

NB NO : *2195*

SERİ NO : *Started with xxxx*

CE Marking Start :

MANISA / TURKEY **Date** 16.11.2017

This declaration is valid for all manufactured CE-marked products from the date of issue until the issue of another declaration or cancellation of this declaration.

Sinem VARDAR
Deputy General Manager

Digitally signed by Iurcu Nicolae
Date: 2022.06.16 13:04:40 EEST
Reason: MoldSign Signature
Location: Moldova