

Manufacturer **ÖZTAŞ GLOBAL SOĞUTMA TEKNOLOJİLERİ VE METAL SANAYİ ve TİCARET ANONİM**
Address **ŞİRKETİ**
ORGANİZE SAN. BÖLGESİ 4. KISIM, AHMET NAZİF ZORLU BULV. NO:32 MANİSA
Product **FREEZER**
Type **MC60ASI - M170ASI- M260ASI - M390ASI - M400ASI -M660ASI - M900ASI- ECO380ASI CLASS - ECO670ASI CLASS- M1600ASI**

The product described above is in conformity with the following EU Directives

- 2014/35/EU REGULATION ON THE ELECTRICAL EQUIPMENT DESIGNED FOR USE WITHIN CERTAIN VOLTAGE LIMITS
- 2014/35/EU ELECTROMAGNETIC COMPATIBILITY REGULATIONS.
- 2006/42/EU MACHINERY DIRECTIVE
- 93/42/EEC MEDICAL DEVICE DIRECTIVE
- 2011/65/EU ROHS DIRECTIVE

The products described above, corresponding to this, bear the CE-mark.

The products described above are in conformity with the following harmonized standards:

SAFETY STANDARDS

- EN ISO 61010-1:2010 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements
- EN ISO 61010-2-011:2017 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-011: Particular requirements for refrigerating equipment
- EMC
- EN ISO 61326-1:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

Öztaş Global Soğutma Teknolojileri ve Metal Sanayi ve Ticaret Anonim Şirketi
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Ref No: CM.TD.06.D02 Rev.Date: 05.01.2022

Ersin ÖZTAŞ
GENERAL MANAGER

ÖZTAŞ
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CERTIFICATE



Medical Devices Quality Management System

CERTIFICATE NO: 31928401

ÖZTAŞ GLOBAL SOĞUTMA TEKNOLOJİLERİ VE METAL SANAYİ VE TİCARET A.Ş.

Keçiliköy OSB Mahallesi Ahmet Nazif Zorlu Bulvar No: 32 YUNUSEMRE MANİSA/TÜRKİYE

EN ISO 13485:2016

**Design, Manufacturing, Sales-Marketing, Technical Service Activities of
Medical Type Refrigerator (Blood Storage, Plasma Storage, Vaccine-
Serum Kit Storage, Ultra Low Temperature Medical Type Freezer)**

Approves that the Medical Devices Quality Management System implemented for above scope.

Issue Date 11.10.2019
Expiry Date 10.10.2022
Revision Date/No 14.03.2022 / 2



TÜRKAK BDS NO
YS-E843-3F0F



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>.