TURQUOISE BIOMEDICAL TECHNOLOGIES

# DECLARATION OF CONFORMITY

**Manufacturer** : TURKUAZ BIYOMEDIKAL TEKN. VE SAG. HIZM. SAN. TIC. LTD. STI.

KAZIM OZALP MAH. HAFTA SOK. NO: 23/2 06610 CANKAYA / ANKARA /TURKEY

We, as manufacturer of this product, herewith declare under our sole responsibility that the below mentioned products:

**Product** : Steam Sterilizer

**GMDN Code** : 38671

**Model Code*** : PLUSTEAM 1S, PLUSTEAM 1M, PLUSTEAM 1L, PLUSTEAM 1XL, PLUSTEAM 2, PLUSTEAM 4, PLUSTEAM 6, PLUSTEAM 8, PLUSTEAM 10, PLUSTEAM 12, PLUSTEAM 14

**Classification** : IIb (According to MDD, Annex IX – Excluding Section 4)

meet the provisions of the following EC Council Directives and Standards. All supporting documentation's are retained under the premises of the manufacturer and the notified body.

**Directives** : Medical Device Directive (MDD 93/42/EEC), Annex II (Excluding Section 4) and 200//47/EC Annex 2.3 requirements. MDD 93/42/EEC and 2007/47/EC Annex 2.3 (Excluding conformity assessment route Annex 4)

**Standards** : Standards applicable to this product are EN 60601-1, EN 60601-1-2, EN 62304, EN 60204-1, EN 285, EN 13445-1, EN ISO 17665-1, EN15223-1, EN 62366, EN 14971, IEC 60529, EN 1041, EN 61010-2-40, EN 61010-1, EN ISO 13485, EN ISO 9001, EN ISO 14001

**Notified Body** : UDEM International Certification Auditing Training Centre Industry and Trade Co.
Mutlukent Mah. 2073. Sok. (Eski 93. Sok) No: 10 Çankaya / ANKARA / TURKEY

**Conf. Asses. Route :** MDD 93/42/EEC and 2007/47/EC Annex 2.3 requirements, excluding annex 4.

TURKUAZ BİYOMEDİKAL TEKNOLOJİLER
VE SAĞ. HİZ. SAN. TİC. LTD. ŞTİ.
Kazım Özalp Mah. Hafta Sok. No: 23/2
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**M. Hilmi MİRELİ**
CEO
01.09.2021

Digitally signed by Matei Andrei
Date: 2022.09.15 13:35:07 EEST
Reason: MoldSign Signature
Location: Moldova

*Expiry Date: 26.08.2023 / Revision: 2021.01*

** When used, "_1" and "_2" used after model codes indicated sub-model mentioning door formation of the indicated models.*

# CERTIFICATE

## TURKUAZ BİYOMEDİKAL TEKNOLOJİLER VE SAĞLIK HİZMETLERİ SAN. TİC. LTD. ŞTİ.

**KAZIM ÖZALP MAH. HAFTA SOK. NO:23/2**
**ÇANKAYA / ANKARA / TÜRKİYE**

*Has been assessed and found to Comply with the Requirements of:*
*Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:*

## ISO 13485:2016

*Medical Devices -Quality Management System is applicable to:*
*Tıbbi Cihazlar Kalite Yönetim Sistemi*

**DESIGN, DEVELOPMENT, PRODUCTION, SALES AND SERVICE OF STEAM STERILIZERS, PLASMA STERILIZERS & DISPOSABLES, LTSF STERILIZERS, AUTOCLAVES, WASHER DISINFECTORS, ULTRASONIC CLEANERS, SEALERS, ETHYLENE OXIDE STERILIZERS, STAINLESS HOSPITAL EQUIPMENTS, CONTAINER SYSTEMS & ACCESSORIES, STERILIZATION & WASHING CONTROL PRODUCTS, STERILIZATION ROLLS AND POUCHES, BOWIE-DICK TEST PACKAGES, CHEMICAL INDICATORS, BIOLOGICAL INDICATORS, AUTOCLAVE TAPES, WRAPPING PAPERS AND DISINFECTANTS & DETERGENTS**

**BUHAR STERİLİZATÖRLERİNİN, PLAZMA STERİLİZATÖRLERİ VE SARFLARININ, LTSF STERİLİZATÖRLERİNİN, OTOKLAVLARIN, YIKAMA VE DEZENFEKSİYON CİHAZLARININ, ULTRASONİK YIKAYICILARIN, POŞET KAPAMA CİHAZLARININ, ETİLEN OKSİT STERİLİZATÖRLERİNİN, HASTANE PASLANMAZ EKİPMANLARININ, KONTEYNER SİSTEMLERİ VE AKSESUARLARININ, YIKAMA VE STERİLİZASYON KONTROL ÜRÜNLERİNİN, STERİLİZASYON RULOLARI VE POŞETLERİNİN, BOWIE-DICK TEST PAKETLERİNİN, KİMYASAL İNDİKATÖRLERİN, BİYOLOJİK İNDİKATÖRLERİN, OTOKLAV BANTLARININ, KREPE KAĞITLARININ VE DEZENFEKTAN VE DETERJANLARIN DİZAYNI, GELİŞTİRMESİ, ÜRETİMİ, SATIŞI VE SERVİSİ**

**Certificate Number: 2021/MDQMS/10112**
**Belge Numarası: 2021/MDQMS/10112**

**Initial Certification Date: 23.03.2021**
**İlk Belgelendirme Tarihi: 23.03.2021**

**Certification Period: 3 Years**
**Belgelendirme Periyodu: 3 Yıl**

**Certificate Validity Date: 22.03.2023**
**Belge Geçerlilik Tarihi: 22.03.2023**

ACCREDITED
Management Systems
Certification Body
MSCB-135

*IQR Sertifikasyon Onayı*

**IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.**
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