



AT-OS Srl | Viale del Lavoro, 19 - 37030 Colognola ai Colli - Verona - ITALY
Tel (+39) 045 6159411 - Fax (+39) 045 6159422
info@at-os.com | www.at-os.com
Partita IVA: IT 02719270239

DECLARATION OF CONFORMITY

Seller : TURKUAZ BIYOMEDIKAL TEKN. VE SAG. HIZM. SAN. TIC. LTD. STI.
KAZIM OZALP MAH. HAFTA SOK. NO: 23/2 06610 CANKAYA / ANKARA /TURKEY

Manufacturer : AT-OS S.r.l.
Viale del Lavoro, 19 Colognola ai Colli (VR) – Italy

We, as manufacturer of this product, herewith declare under our sole responsibility that the below mentioned products designed especially for the seller mentioned above:

Product : Machine for washing and disinfection

UMBNS Code : 17671

Model Code : PLUSHER WDC 8, PLUSHER WDS 12, PLUSHER WDS18

Classification : IIb (According to MDD, Annex IX)

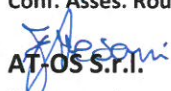
meet the provisions of the following EC Council Directives and Standards. All supporting documentation's are retained under the premises of the manufacturer and the notified body.

Directives : Medical Device Directive – COUNCIL DIRECTIVE of 14 June 1993 concerning medical devices (MDD 93/42/EEC), Annex I; 2007/47/EEC: updating to Medical Device Directive 93/42/EEC.

Standards : Standards applicable to this product are EN ISO 13485:2012; DIN EN 1717:2001; DIN EN 13077:2004; EN 61010-1:2010; EN 61010-2-040:2005; EN 61326-1:2006 + Recommendation NB-MED/2.12 Rec 1; EN ISO 15883-1:2009; EN ISO 15883-2:2009.

Notified Body : TÜV SÜD Product Service GmbH.
Ridler Str. 65, D-80339 München, Germany

Conf. Asses. Route : Annex II.3.


AT-OS S.r.l.
Francesco Avesani
(Regulatory Office)

06.09.2017



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



IQR Sertifikasyon Onayı

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