

ADDRESS: KAZIM ÖZALP MAHALLESİ HAFTA SOKAK NO: 23/2
ÇANKAYA/ANKARA TÜRKİYE

Certify that the Medical Devices Quality Management System of the above organization has been audited and found to be in accordance with the requirements of standard detailed below.

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

This certification was conducted in accordance with the qacs international f.z.c auditing and Certification procedures and it is remain valid subject to annual surveillance audits.

1st Surveillance Date : 14th March 2020
2nd Surveillance Date : 14th March 2021
Expiry Date:- 14th March 2022

Note: Certificate shall be valid after surveillance, only if continuation letter by QACS is present.



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CERTIFICATION
SERVICES



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EEC CERTIFICATE

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II

Company Name : Turkuaz Biyomedikal Teknolojiler Ve Sağ. Hizm. San. Tic. Ltd. Şti.

Company Address : Kazım Özalp Mah. Hafta Sokak No:23/2 06610 Çankaya /
ANKARA / TURKEY

Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive - Annex II
(Excluding Section 4)

Product : Steam Sterilizer - Class IIb

Models : PLUSTEAM 1S, PLUSTEAM 1M, PLUSTEAM 1L, PLUSTEAM 1XL, PLUSTEAM 2,
PLUSTEAM 4, PLUSTEAM 6, PLUSTEAM 8, PLUSTEAM 10, PLUSTEAM 12, PLUSTEAM 14

GMDN : 38671

Certificate Number : M.2018.106.10272

Report Number : MD.3654.IB

Initial Assessment Date : 02.03.2018

Registration Date : 27.08.2018

Revision Date /No : 28.08.2018/01

Expiry Date : 26.08.2023

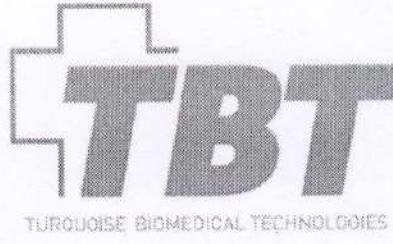
UDEM hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design-examination certificate is required for placing the Class III devices on the market. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The currency of the certificate can be checked through www.udem.com.tr.


UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.

CE
2292



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2014/30/EU DECLARATION OF CONFIRMITY

We hereby declare that below listed products are in conformance with 2014/30/EU conditions. All necessary documents are held within the premises of manufacturer.

Company Name : Turkuaz Biyomedikal Teknoloji ve Saę. Hiz. San. ve Tic. Ltd. řti.

Address : Kazım Özalp Mah. Hafta Sok. No: 23/2 06610 Çankaya / ANKARA / TURKEY

Tel / Fax : +90 850 840 8 828 / +90 312 911 25 28

Web / E-mail : www.tbmedical.com / info@tbmedical.com

Product : Steam Sterilizer

Model : PLUSTEAM series

UNSPSC Code : 42281508

GMDN Code : 38671

Classification : 2014/30/EU Electromagnetic Compatibility Regulation (EMC) – EN 60601-1-2

We declare that PLUSTEAM 1S, PLUSTEAM 1M, PLUSTEAM 1L, PLUSTEAM 1XL, PLUSTEAM 2, PLUSTEAM 4, PLUSTEAM 6, PLUSTEAM 8, PLUSTEAM 10, PLUSTEAM 12, PLUSTEAM 14 "Steam Sterilizers" are complying 2014/30/EU Electromagnetic Compatibility Regulation's requirements.

TURKUAZ BIYOMEDİKAL TEKNOLOJİLER
VE SAę. HİZ. SAN. TİC. LTD. řTİ.
Kazım Özalp Mah. Hafta Sok. No: 23/2
G.O.P. - Çankaya / ANKARA / TURKEY
Tel: +90 850 840 8 828 Fax: +90 312 911 25 28
Cumhurbaşkanlığı Mersis No: 0871052153300016

M. Hilmi MİRELİ

CEO

01/02/2019, Rev.1

Expiry Date: 26.08.2023



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