EC 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

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Date: 2021.04.16 16:21:45 EEST
Reason: MoldSign Signature
Location: Moldova

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

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.

CE 2292

Addres: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr