S.A. M-INTER-FARMA

IDNO 1003600005263 Cod OKPO 37020536 Cod TVA 0207934
MD 2025, Chișinău, strada Grenoble 21, 23, Moldova

Nr. 195 din "23" Decembrie 2019

IMSP ASOCIAȚIA MEDICALĂ TERITORIALĂ BOTANICA
Către grupul de lucru la
COP nr. ocds-b3wdp1-MD-1576244492787,
din 24.12.2019

DECLARAȚIE

Prin prezenta „M-INTER-FARMA" S.A., confirmă obligațiunea de a instala piesele oferite în cadrul COP nr. ocds-b3wdp1-MD-1576244492787 din 24.12.2019, de către un inginer calificat al companiei și de a efectua reglării dispozitivului medical, termenul de garanție fiind de 3 luni.

Cu respect,
Director "M-INTER-FARMA" S.A. Morozov Maria

Digitally signed by Palii Nina
Date: 2019.12.24 10:33:29 EET
Reason: MoldSign Signature
Location: Moldova

Certificate

OF TRAINING

TBT

PROUDLY PRESENTED TO

LUNGU ION

FOR SUCCESSFUL COMPLETING ALL REQUIREMENTS FOR

"INSTALLATION, OPERATION, MAINTENANCE & TROUBLESHOOTING TRAINING FOR
PLUSTEAM SERIES STEAM STERILIZERS & PLUSHER SERIES WASHER DISINFECTORS"

BETWEEN 08-13 NOVEMBER 2019, IN MOLDOVIA.

15.11.2019

DATE

SIGNATURE

Certificate No: 2019/007 F.14.06-1 / 01.06.19

Certificate

OF TRAINING

TBT

PROUDLY PRESENTED TO

PISLARU CORNEL

FOR SUCCESSFUL COMPLETING ALL REQUIREMENTS FOR

"INSTALLATION, OPERATION, MAINTENANCE & TROUBLESHOOTING TRAINING FOR
PLUSTEAM SERIES STEAM STERILIZERS & PLUSHER SERIES WASHER DISINFECTORS"

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DATE

SIGNATURE

Certificate No: 2019/007 F.14.06-1 / 01.06.19

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
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

UDEM

Address: 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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 15 05 41151 010

Manufacturer: **AT-OS S.r.l.**
Viale del Lavoro 19
37030 Colognola ai Colli (VR)
ITALY

Facility(ies): AT-OS S.r.l.
Viale del Lavoro 19, 37030 Colognola ai Colli (VR), ITALY

Product Category(ies): **Washer-disinfectors for non active medical devices**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: ITA260823

Valid from: 2015-07-06
Valid until: 2020-07-05

665293

Date, 2015-06-29

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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