



E C C E R T I F I C A T E

Production Quality Assurance for Medical Devices Directive 93/42/EEC Annex V

Company Name : Turkuaz Sağlık Hizmetleri Medikal Temizlik Kimyasal Ürünler
San. ve Tic. A.Ş.

Company Address : Yakuplu Mah. Birlik Cad. No:32/1 İç Kapı No:1 Beylikdüzü
İSTANBUL / TURKEY

Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive - Annex V

Product : Sterile Antifog Solution - Class IIa
Sterile Obstetric Gel - Class IIa
Non-sterile Lubricant Gel - Class IIa
Sterile Lubricant Gel - Class IIa
Non-sterile Paraben-Free Lubricant Gel - Class IIa

QMDN : 45225, 60796, 33587, 60796, 34131

Certificate Number : M.2018.106.9536

Report Number : MD.3561.IB

Initial Assessment Date : 31.01.2018

Registration Date : 18.04.2018

Revision Date /No : 03.05.2018/01

Expiry Date : 12.04.2023


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

CE
2292

UDEM hereby declares that the requirements of annex V, of the directive 93/42/EEC have been met for the (re)products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex V, section 4 of the mentioned directive. According to Annex V, section 4 an EC design examination certificate is issued for placing the Class II 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 immediately. The above named company and UDEM must keep a copy of this certificate for 5 years from the date of issue of the certificate. UDEM is under the responsibility of the manufacturer for the compliance of the CE Declaration of Conformity. The above mentioned company must notify any changes related to the approved products (UDEM) to UDEM. UDEM will not renew the expiry date of this certificate in question. The mentioned company and UDEM are adding the product on the market. The validity of the certificate can be renewed through the UDEM system.

Address: Muğent Mahallesi 2078 Sokak (Eski 93 Sokak, No:10 Çankaya - Ankara - TÜRKİYE)
Phone: +90 0312 443 03 90 Fax: +90 0312 443 03 75
E-mail: info@udemint.com.tr www.udemint.com.tr