EC DECLARATION OF CONFORMITY

MANUFACTURER : ISTEM MEDIKAL TIBBİ CİHAZ ve SAN. TİC. LTD. ŞTİ

ADDRESS :ANADOLU OSB MAH. 29 EKİM CAD. NO:41 MALIKÖY-SİNCAN/ANKARA TURKEY

PRODUCT : Sterile Lubricant Gel with Lidocaine (6 ml, 11ml prefilled gel in syringe and 12,5 g prefilled gel in accordion tube)

MODEL : It is given in the attached list.

GMDN: 60796

CLASSIFICATION: CLASS III, ANNEX-IX, RULE 5, RULE13

CONFORMITY ASSESSMENT ROUTE: ANNEX II (including section 4)

APPLICABLE STANDARDS: EN ISO 13485:2016, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11137-3:2017, EN 868-2:2017, EN 868-3:2017, EN ISO 11737-1:2018, EN ISO 11737-2:2020, EN ISO 14971:2019, EN ISO 10993-1:2021, EN ISO 10993-3:2015, EN ISO 10993-5:2010, EN ISO 10993-10:2014, EN ISO 15223-1:2016, EN ISO 19011:2018, EN ISO 14644-1:2016, EN ISO 14644-2:2016, EN ISO 14644-3:2019, EN ISO 14155:2020, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 7886-1:2018, EN ISO 80369-7:2017, EN 980:2011, EN 1041:2008(A1:2014), EN ISO 17050-1:2013, EN ISO 17050-2:2007, TS EN 62366-1:2015, MDD 93/42 EEC, MEDDEV 2.7.1 Rev 4:2016, MEDDEV 2.12-1 rev8:2013, MEDDEV 2 12-2 rev2:2012, MEDDEV 2.4/1:rev9:2010, MEDDEV 2.5/5:Rev 3:1998, ASTM F1980-16

Pharmacopoeia monographs: USP 35/Page 1191, EP 07/2010:0658, EP 09/2017 2.2 1-2.2.2, EP 09/2017 2.9.17, EP 09/2017 2.2.10, EP 09/2017 2.6.1, EP 09/2017:0409, EP 09/2017:0431

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC AND 2007/47/EC FOR MEDICAL DEVICES AND THESE PRODUCTS ARE NOT USED FOR MEDICINE. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER

NAME OF NOTIFIED BODY: NB 2292 - UDEM Uluslararasi Belgelendirme Denetim [illegible] San. ve Tic. A.Ş.
Address: Mutlukent Mah. 2073 Sk. No:10 Çankaya, ANKARA / TURKEY

SOCIETATEA COMERCIALA STERIL ROMANIA S.R.L. 2 BUCUREŞTI - ROMANIA

EC CERTIFICATE NUMBER: M.2021.106.14615
Registration Date: 24.05.2021 **Expiry Date:** 27.05.2024

EC DESIGN EXAMINATION CERTIFICATE NUMBER: M.2021.106.14615-1
Registration Date: 24.05.2021 **Expiry Date:** 27.05.2024

PLACE, DATE OF ISSUE: ANKARA, 25.05.2021

SIGNATURE:

LEVENT HAYYAOĞLU
GENERAL MANAGER
ISTEM MEDİKAL

NAZMİYE CUMALI
QUALITY ASSURANCE MANAGER

MODELLER

Ticari Marka	Barkod	Referans Numarası	Tanım
AQUTOUCH Jelly	8698703339057	ATG-L 006	AQUA TOUCH Jelly Steril Kaydırıcı Jel-Lidokain içerikli 6ml
	8698703339064	ATG-L 011	AQUA TOUCH Jelly Steril Kaydırıcı Jel-Lidokain İçerikli 11ml
	8699415727705	ATG-L 12.5	AQUA TOUCH Jelly Steril Kaydırıcı Jel-Lidokain İçerikli 12.5 g

MODELS

Trade Mark	Barcode	Referance Number	Definition
AQUTOUCH Jelly	8698703339057	ATG-L 006	AQUTOUCH Jelly Sterile Lubricant Gel with Lidocaine-6ml Prefilled Syringe
	8698703339064	ATG-L 011	AQUTOUCH Jelly Sterile Lubricant Gel with Lidocaine-11ml Prefilled Syringe
	8699415727705	ATG-L 12.5	AQUTOUCH Jelly Sterile Lubricant Gel with Lidocaine-12.5g Prefilled Accordion Tube

SOCIETATEA COMERCIALĂ STERIL ROMANIA S.R.L. 2 BUCUREȘTI - ROMÂNIA

Traducere din limba engleză

DECLARAŢIE DE CONFORMITATE CE

PRODUCATOR:	ISTEM MEDIKAL TIBBI CIHAZ ve SAN.TIC.LTD.STI.
ADRESA:	ANADOLU OSB MAH. 29 EKIM CAD. NO:41 MALIKOY-SINCAN/ANKARA TURCIA
PRODUS:	Gel lubrifiant steril cu lidocaina (seringa preumpluta cu gel 6 ml, 11 ml si tub acordeon preumplut cu gel 12,5 gr)
MODEL:	Sunt mentionate in lista atasata
GMDN:	60796
CLASIFICARE:	CLASA III, ANEXA IX, REGULA 5, REGULA 13
TRASEU DE EVALUARE A CONFORMITATII:	ANEXA II (INCLUSIV SECTIUNEA 4)

STANDARDE APLICABILE: EN ISO 13485:2016, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11137-3: 2017, EN 868-2:2017, EN 868-3:2017, EN ISO 11737-1:2018, EN ISO 11737-2:2020, EN ISO 14971:2019, EN ISO 10993-1:2021, EN ISO 10993-3:2010, EN ISO 10993-5:2010, EN ISO 10993-10:2014, EN ISO 15223-1:2016, EN ISO 19011:2018, EN ISO 14644-1:2016, EN ISO 14644-2:2016, EN ISO 14644-3:2019, EN ISO 14155:2020, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 7886-1:2018, EN ISO 80369-7:2017, EN 980:2011, EN 1041:2008(A1:2014), EN ISO 17050-1:2013, EN ISO 17050-2:2007, TS EN 62366-1:2015, MDD 93/42/EEC, MEDDEV 2.7.1:Rev.4:2016, MEDDEV 2.12-1:Rev.8:2013, MEDDEV 2.12-2:Rev.2:2012, MEDDEV 2.4/1:Rev.9:2010, MEDDEV 2.5/5:Rev.3:1998, ASTM F1980-16

Monografii farmacopee: USP 35/Pagina 1191, EP 07/2010:0658, EP 09/2017 2.2.1-2.2.2, EP 09/2017 2.9.17, EP 09/2017 2.2.10, EP 09//2017 2.6.1, EP 09/2017:0409, EP 09/2017:0431

PRIN PREZENTA DECLARAM CA PRODUSELE MAI SUS MENTIONATE INDEPLINESC DISPOZITIILE DIRECTIVEI CONSILIULUI 93/42/EEC SI 2007/47/EC PENTRU DISPOZITIVE MEDICALE SI CA ACESTE PRODUSE NU SUNT UTILIZATE CA MEDICAMENTE. TOATE DOCUMENTELE JUSTIFICATIVE SUNT PASTRATE LA SEDIUL PRODUCATORULUI.

NUMELE ORGANISMULUI NOTIFICAT: NB 2292 - UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. Ve Tic. A.S.

Adresa: Mutlukent Mah. 2073 Sk. No:10 Cankaya, ANKARA TURCIA

NUMARUL CERTIFICATULUI CE: M.2021.106.14615
Data emiterii: 24.05.2021 **Data expirare:** 27.05.2024

NUMARUL CERTIFICATULUI CE DE EXAMINARE DE PROIECT: M.2021.106.14615-1
Data emiterii: 24.05.2021 **Data expirare:** 27.05.2024

SOCIETATEA COMERCIALA STERIL ROMANIA S.R.L. 2 BUCUREŞTI - ROMANIA

LOC, DATA EMITERII: ANKARA, 25.05.2021

SEMNATURA:

LEVENT HAYYAOGLU
DIRECTOR GENERAL
Stampila si semnatura

NAZMIYE CUMALI
DIRECTOR ASIGURAREA CALITATII
Semnatura indescifrabila

MODELE

Marca	Cod de bare	Cod produs	Descriere
AQUATOUCH Jelly	8698703339057	ATG-L 006	Gel lubrifiant steril AQUATOUCH Jelly cu lidocaina – seringa preumpluta de 6 ml
	8698703339064	ATG-L 011	Gel lubrifiant steril AQUATOUCH Jelly cu lidocaina – seringa preumpluta de 11 ml
	869415727705	ATG-L 12.5	Gel lubrifiant steril AQUATOUCH Jelly cu lidocaina – tub acordeon preumplut cu 12,5 gr

SOCIETATEA COMERCIALA STERIL ROMANIA S.R.L. 2 BUCUREȘTI - ROMÂNIA

EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2021.106.14615-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: İstem Medikal Tıbbi Cihaz ve San. Tic. Ltd. Şti.
Company Address	: Anadolu Organize Sanayi Bölgesi Mah. 29 Ekim Cad. No:41 Malıköy Sincan ANKARA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Sterile Lubricant Gel with Lidocaine - Class III
GMDN	: 60796

SOCIETATEA COMERCIALA STERIL ROMANIA S.R.L. 2 BUCURESTI - ROMANIA

This certificate has been issued based on Ministry of Health's E-61749811-511.14-437042 numbered scientific opinion taken on 20.05.2021 according to 93/42/EEC Annex I Art .7.4

Certificate Number	: M.2021.106.14615
Report Number	: MD.3200.IB
Initial Assessment Date	: 12.03.2021
Registration Date	: 24.05.2021
Revision Date /No	: -
Expiry Date	: 27.05.2024

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 93/42/EEC Directive 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. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returnedupon 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 thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned

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

Traducere din limba engleză

UDEM

CERTIFICAT CE
Sistem complet de asigurare a calitatii
Directiva pentru Dispozitive Medicale 93/42/EEC Anexa II (exclusiv Sectiunea 4)

M.2021.106.14615-1 Certificatul de Examinare Proiect a fost pregatit pentru Produsele de clasa III definite in acest certificat

Denumire companie:	Istem Medikal tibbi Cihaz ve San. Tic. Ltd. Sti.
Adresa companiei:	Anadolu Organize Sanayi Bolgesi Mah. 29 Ekim Cad. No:41 Malikoy Sincan ANKARA / TURCIA
Directive si Anexe conexe:	Directiva pentru Dispozitive Medicale 93/42/EEC – Anexa II (exclusiv Sectiunea 4)
Produs:	Gel steril lubrifiant cu lidocaina – Clasa III
GMDN:	60796

Acest certificat a fost emis in baza deciziei stiintifice a Ministerului Sanatatii din 20.05.2021 cu numarul E-61749811-511.14-437042 conform 93/42/EEC Anexa I Art.7.4.

Numar certificat:	M.2021.106.14615
Numar raport:	MD.3200.IB
Data evaluare initiala:	12.03.2021
Data inregistrare:	24.05.2021
Data/nr.revizie:	-
Data expirare:	27.05.2024

Semnatura indescifrabila
UDEM International Certification Auditing Training Centre Industry and Trade Co.Ltd.
CE2292

UDEM declara prin prezenta ca cerintele Anexei II, exclusiv sectiunea 4, a Directivei 93/42/EEC au fost indeplinite pentru produsele enumerate. Producatorul mai sus mentionat a implementat si aplica un sistem de asigurare a calitatii, care suporta audituri periodice de verificare, definit prin Anexa II, sectiunea 5 a directivei mentionate. In conformitate cu Anexa II, sectiunea 4, este necesar un Certificat CE de examinare proiect pentru introducerea pe piata a dispozitivelor de Clasa III. Responsabilitatea UDEM pentru dispozitivele de clasa I acoperite de certificatul CE este limitata la probleme de fabricatie legate de protejarea si mentinerea conditiilor sterile, daca dispozitivul este steril; si la probleme de fabricatie legate de conformitatea produselor cu cerintele metrologice, daca are functie de masurare. Acest certificat ramane proprietatea UDEM International Certification Auditing Training Centre Industry and Trade Co.Ltd. caruia trebuie sa ii fie returnat la solicitare. Mai sus mentionata companie si UDEM trebuie sa pastreze o copie a acestui certificat timp de 5 ani de la inregistrarea certificatului. Utilizarea marcajului CE cade in responsabilitatea producatorului prin completarea Declaratiei de Conformitate CE. Compania mai sus mentionata trebuie sa notifice UDEM modificarile legate de aprobarea produselor de catre UDEM. Daca UDEM nu reinnoieste data de expirare a acestui certificat, compania mentionata trebuie sa inceteze introducerea produsului pe piata.

SOCIETATE COMERCIALA STERIL ROMANIA S.R.L. 2 BUCURESTI - ROMANIA

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