EC CERTIFICATE

Full Quality Assurance System

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

M.2020.106.13505-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: Turkuaz Sağlık Hizmetleri Medikal Temizlik Kimyasal Ürünler San. ve Tic. A.Ş.
Company Address	: Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad. No: 45/5, 34522, Esenyurt İSTANBUL / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Sterile Catheter Gel with Lidocaine (Konix Lido C Sterile Catheter Gel) - Class III
GMDN	: 60796

This certificate has been issued based on Ministry of Health's 68869993-511.14-E8880 numbered scientific opinion taken on 08.04.2020 according to 93/42/EEC Annex I Art .7.4

Certificate Number	: M.2020.106.13505
Report Number	: MD.3561.IB
Initial Assessment Date	: 21.06.2019
Registration Date	: 10.04.2020
Revision Date /No	: 12.03.2021/01
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

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EC DESIGN EXAMINATION CERTIFICATE

93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2020.106.13505 the validity of the certificate M.2020.106.13505-1 will also end.

Company Name	: Turkuaz Sağlık Hizmetleri Medikal Temizlik Kimyasal Ürünler San. ve Tic. A.Ş.
Company Address	: Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad. No: 45/5, 34522, Esenyurt İSTANBUL / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive – Annex II (Section 4)
Product	: Sterile Catheter Gel with Lidocaine (Konix Lido C Sterile Catheter Gel) - Class III
GMDN	: 60796

This certificate has been issued based on Ministry of Health's 68869993-511.14-E8880 numbered scientific opinion taken on 08.04.2020 according to 93/42/EEC Annex I Art .7.4

Certificate Number	: M.2020.106.13505-1
Report Number	: MD.3561.IB
Initial Assessment Date	: 21.06.2019
Registration Date	: 10.04.2020
Revision Date /No	: 12.03.2021/01
Expiry Date	: 27.05.2024

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

The EC desing examination certificate refers to the above mentioned product. UDEM hereby declares that the requirements of Annex II, 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 aforementioned directive. 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 validity of the certificate can be checked through www.udem.com. tr.

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10000 Zagreb, CROATIA

2023/05/15

Turkuaz Sağlık Hizmetleri Medikal Temizlik
Kimyasal Ürünler Sanayi ve Ticaret A.Ş.
Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad.
No: 45/5 Esenyurt, İstanbul, Türkiye

NOTIFIED BODY CONFIRMATION LETTER

Reference: 2023.MDR.1060.NBCL.0005

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, UDEM ADRIATIC D.O.O., a Notified Body (NB) designated under Regulation (EU) 2017/745 (MDR) and identified by the number 2696 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR (on the date of 2022/11/16) and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR (on the date of 2022/11/16) with the following manufacturer:

Turkuaz Sağlık Hizmetleri Medikal Temizlik

Kimyasal Ürünler Sanayi ve Ticaret A.Ş.

Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad.

No:45/5 Esenyurt, İstanbul, Türkiye

SRN Number (if available): TR-MF-000015402

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which UDEM Adriatic d.o.o. is also responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD). Table 2 identifies the devices for which an MDR application has been received and a

written agreement concluded, but UDEM Adriatic d.o.o. has not yet taken the responsibility for appropriate surveillance of the corresponding devices under MDD.

In the case of devices covered by certificates issued under MDD that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 March 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of UDEM Adriatic d.o.o.

Zekeriya AYTAÇ

General Manager

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Table 1: Devices covered by this letter and for which UDEM Adriatic d.o.o. is also responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Table 2: Devices covered by this letter and for which UDEM Adriatic d.o.o. is NOT responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Obstetric Gel	Class IIb excluding Class IIb implantable non-WET	N/A	**Certificate 1:** Production Quality Assurance Certificate No: M.2018.106. 9536 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)
Konix Lido Sterile Catheter Gel (Chlorhexidine Gluconate)	Class III	N/A	**Certificate 1:** Full Quality Assurance System Certificate No: M.2021.106. 14604 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292) **Certificate 2:** EC Design Examination Certificate No: M.2021.106. 14604-1 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)

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Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Konix Lido Sterile Catheter Gel with Lidocain	Class III	N/A	**Certificate 1:** Full Quality Assurance System Certificate No: M.2021.106. 14603 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292) **Certificate 2:** EC Design Examination Certificate No: M.2021.106. 14603-1 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)
Konix Lido+ Chlorhexidine Sterile Catheter Gel, with Lidocain	Class III	N/A	**Certificate 1:** Full Quality Assurance System Certificate No: M.2020.106. 13505 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292) **Certificate 2:** EC Design Examination Certificate No: M.2020.106. 13505-1 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)
Aromatic and Steril /Nonsteril Nonaromatic Lubricant Gels (In case of Lubricants specifically intended for use together with medical devices (e.g. for gloves, endoscopes, condoms))	Class IIb excluding Class IIb implantable non-WET	N/A	**Certificate 1:** Production Quality Assurance Certificate No: M.2018.106. 10376 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			Certificate 2: Production Quality Assurance Certificate No: M.2018.106. 9536 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292) **Certificate 3:** Production Quality Assurance Certificate No: M.2021.106. 14521 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292) **Certificate 4:** Production Quality Assurance Certificate No: 0425-MED-004476-00 ICIM S.p.A. (NB0425)
Sterile Ultrasound Gel (invavize usage& body surface)	Class IIb excluding Class IIb implantable non-WET	N/A	**Certificate 1:** Full Quality Assurance System Certificate No: M.2018.106. 9377 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)
Antifog Solution	Class IIb excluding Class IIb implantable non-WET	N/A	**Certificate 1:** Production Quality Assurance Certificate No: M.2018.106. 9536 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)

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Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/05/15	2023.MDR.1060.NBCL.0005	Initial issue

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