



EC Certificate Production Quality Assurance System: Certificate US19/819943513

The management system of

MedOne Surgical, Inc.

670 Tallevast Road, Sarasota, FL, 34243, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex V

For the following products

Sterile ophthalmic devices: cannulae, brushes, picks and related accessories (tubing, backflush devices and injection kits), knives and forceps for ophthalmic surgery.

For placing on the market of Class IIb covered by this certificate, an EC Type Examination Certificate according to Annex III is required.

This certificate is valid from 16 December 2019 until 11 April 2024
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 14 February 2003
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/MC/ 208342

Authorised by

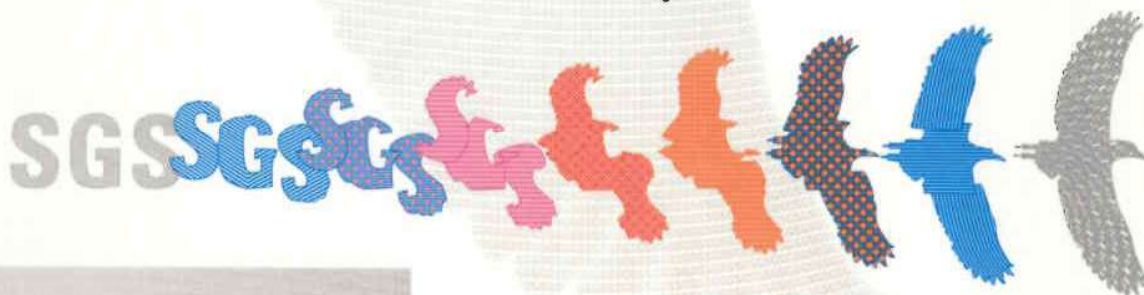
Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5008 - Certificate CE1639 AnnexV_EN rev. 01

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Manufacturer's Declaration

In relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices , in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	MedOne Surgical, Inc.
Manufacturer address and contact details	670 Tallevast Road Sarasota, Florida, USA 34243
Single Registration Number (SRN) (if available)	US-MF-000002763

Authorised Representative name (if applicable)	Advena, Ltd.
Authorised Representative address and contact details	Tower Business Centre 2nd Flr., Tower Street Swatar, BKR 4013 Malta
Single Registration Number (SRN) (if available)	MT-AR-000000234

Notified body name (if applicable)	SGS House Noordertaan
Notified body number (if applicable)	1639
Directive Certificate number(s) to which this confirmation is made (if applicable)	US19/819943513
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	11 April 2024
End date of extended validity/transition period	31 Dec 2028

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.



MedOne Surgical, Inc.
670 Tallevast Road
Sarasota, FL 34243 USA



Tel: 941.359.3129
Fax: 941.359.1708



www.MedOne.com



We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements:

☐ Expired *before* 20 March 2023:

- ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
- ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
- ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body



☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

✓ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

✓ ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

✓ ☒ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

MedOne Surgical, Inc.

Sarasota, Florida, USA

March 7, 2024

Bruce Beckstein

President, MedOne Surgical, Inc.

Bbeckstein@medone.com



MedOne Surgical, Inc.
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Sarasota, FL 34243 USA



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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Part / Catalogue Number	Description / Name	Notified Body name and number where the MDR application was lodged/contract signed
3200	Viscous Fluid Cannula 20g (4mm)	SGS Belgium NV (1639)
3201	Viscous Fluid Cannula 20g (6mm)	
3202	Infusion Cannula 20g (4mm)	
3203	Infusion Cannula 20g (6mm)	
3204	MicroPick 25g	
3205	Cannula XL 20g	
3206	Cannula XL 23g	
3207	Cannula XL 25g	
3208	FlexTip™ Cannula XL 20g (3mm)	
3209	FlexTip™ Cannula XL 23g (3mm)	
3210	FlexTip™ Cannula XL 25g (3mm)	
3211	FlexTip™ Cannula 20g (6mm)	
3214	Cannula 20g	
3215	FlexTip™ Brush 20g	
3218	PolyTip® Cannula 25g/31g	
3219	PolyTip® Cannula 25g/38g	
3220	FlexTip™ Cannula 25g (3mm)	
3221	FlexTip™ Cannula 25g (1mm)	
3222	FlexTip™ Brush 25g	
3223	Extension Tube [Hammer]	
3224	FlexTip™ Cannula 25g (5mm)	
3225	Cannula 25g	
3226	VFI Cannula 25g	
3228	Backflush Handle	
3229	MicroPick 23g	
3230	FlexTip™ Cannula 23g (1mm)	
3231	FlexTip™ Cannula 23g (3mm)	
3232	FlexTip™ Brush 23g	
3233	PolyTip® Cannula 23g/38g	
3234	Cannula 23g	
3235	VFI Cannula 23g	
3237	Dual Bore Cannula 20g	
3238	FlexTip™ Cannula 20g (1mm)	
3239	Dual Bore Cannula 23g	
3240	Dual Bore Cannula 25g	
3241	PolyTip® VFI Cannula 23g (10mm)	
3242	FlexTip™ Cannula 23g (5mm)	
3243	High Pressure Extension Tube	



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3245	VFI Infusion Cannula 25g	
3246	VFI Infusion Cannula 23g	
3247	Extendable PolyTip® Cannula 25g/38g	
3248	Extendable PolyTip® Cannula 23g/38g	
3251	FlexTip™ Cannula 25g (0.75mm)	
3252	FlexTip™ Cannula 23g (0.75mm)	
3254	PolyTip® Cannula 23g/38g (2mm)	
3255	PolyTip® Cannula 25g/38g (2mm)	
3256	PolyTip® Cannula 27g/38g (2mm)	
3257	Cannula 27g	
3258	FlexTip™ Cannula 27g (1mm)	
3259	PolyTip® Cannula 27g/38g	
3260	FlexTip™ Cannula 27g (0.75mm)	
3261	MicroTip Beveled Cannula 25g/40g	
3262	PolyTip® Cannula 25g/33g (2mm)	
3263	Nano Cannula 25g/48g	
3264	FlexTip™ Brush 27g	
3273	VFI Cannula 27g	
3274	Visco Dissection Cannula 25g	
3275	MicroDose™ Injection Kit	
3276	Backflush Cannula 27g	
3278	Backflush FlexTip™ 27g	
3286	Backflush Cannula 23g	
3290	Backflush FlexTip™ 23g	
3295	Backflush Cannula 25g	
3296	Backflush FlexTip™ 25g	
3298	Extendable FlexTip™ Cannula 25g	
3299	Extendable FlexTip™ Cannula 23g	
3300	Oil Removal Cannula 23g [Kapran]	
3301	VFI Infusion Cannula 27g	
3302	Backflush SidePort 27g	
3305	PolyVent™ Cannula 25g/38g	
3306	PolyVent™ Cannula 23g/38g	
3307	Extendable PolyVent™ Cannula 25g/38g	
3308	Extendable PolyVent™ Cannula 23g/38g	
3311	Olive Tip SC Cannula 23g [El Rayes]	
3319	PolyTip® Cannula 25g/38g Set	
3423	DualBore SideFlō® Cannula 23g	
3425	DualBore SideFlō® Cannula 25g	
3427	DualBore SideFlō® Cannula 27g	
3507	Extendable PolyTip® Cannula 25g/38g [Shiraga]	
3508	Extendable FlexTip™ Brush 25g	



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April 7, 2024

**Important Notice from MedOne Surgical, Inc.
Extension of MDD Directive 93/42/EEC**

**Re: Extension of MDD Directive 93/42/EEC on Medical Devices, Annex V Certificate:
US19/819943513, Class IIa, Sterile ophthalmic devices: cannulae, brushes, picks and
related accessories (tubing, backflush devices and injection kits) for ophthalmic surgery.**

To Whom It May Concern:

As you may be aware, the current MedOne EU Medical Device Directive Certificate expires on 11 April 2024. This letter is to serve as notification that MedOne's **MDD Certificate is hereby extended to 31 December 2028**, in accordance with the conditions of Article 120(3c) of the Medical Device Regulation MDR 2017/745.

Please be aware that Notified Bodies are not permitted to issue new MDD Certificates for MDD legacy devices under this same article. Legacy devices are those devices currently CE marked under prevailing MDD Certificates.

During the transitional period, between expiring MDD Certificates and the issuance of new MDR Certificates, the MDD CE certificate may be extended as long as the provisions in Article 120(3c) are fulfilled by the Manufacturer. MedOne has met all requirements and is providing the attached Manufacturer's Declaration, affirming compliance.

Additionally, MedOne notified body SGS – Belgium (1639), has provided the attached Confirmation Letter affirming receipt of formal application and execution of a written agreement, both in accordance with Annex VII of MDR. This letter endorses the continued compliance of MedOne devices to **31 December 2028**, as specified by the appropriate transition timeline presented in Article 120(3) of MDR (as amended by EU 2023/607).

As an MDR status update, MedOne has successfully passed two onsite MDR audits by our Notified Body, with no findings. The Technical Documentation audit is nearing completion, and represents the final step for approval of a MDR Certificate. Upon receipt, this MDR Certificate will be available immediately for distribution, as well as posted on the company website at www.MedOne.com.

We thank you for your understanding during this certificate transition, as well as your continued support of MedOne Products.

Sincerely,



Paul Butcher
RA/QA Manager

**Attachment(s): MedOne Surgical, Inc. MDR Manufacturer's Declaration – CE Mark Extension
SGS – Belgium Confirmation Letter Reference: CLNB1639 - 208342**



MedOne Surgical Inc.
670 Tallevast Road,
Sarasota,
FL 34243,
United States of America

08-April-2024

Confirmation Letter Reference: CLNB1639 - 208342

To whom it may concern,

Confirmation of receipt 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, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

MedOne Surgical Inc.
670 Tallevast Road,
Sarasota,
FL 34243,
United States of America
SRN Number: US-MF-000002763

EU Authorized Rep:
Advena Ltd.
Tower Business Centre 2nd Floor,
Tower Street Swatar,
BKR 4013
Malta
SRN Number: MT-AR-000000234

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the

NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (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/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

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 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st 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)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st 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 the Notified Body SGS Belgium NV NB1639,



Ian How
PP

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	MDD Device name (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Cannulae Family: Cannulas and accessories (cannulae, brushes, picks and related accessories (tubing, backflush devices and injection kits). Basic UDI: 081131301MEDSURG01QY	Class IIa	Sterile ophthalmic devices: cannulae, brushes, picks and related accessories (tubing, backflush devices and injection kits)	N/A	Certificate #1; US19/819943513 NB: 1639

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

"N/A: NB1639 is responsible for appropriate surveillance. "

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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
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N/A: NB1639 is responsible for appropriate surveillance			
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Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/03/21	Version 1	Initial issue
2024/04/08	Version 2	Updating the Basic UDI number

SGS NB1639 - Confirmation letter Regulation (EU) 2023/607



UDEM Adriatic d.o.o.
Radnička cesta 54/R3
10000 Zagreb, CROATIA

2023/12/15

TEKNOMEK MEDIKAL MALZEME SAN. VE TIC. LTD. ŞTİ.
Karamahmet Mahallesi
Avrupa Serbest Bölgesi 9.Sk. No:14
Ergene, Tekirdağ, Türkiye

NOTIFIED BODY CONFIRMATION LETTER

Reference: 2023.MDR.1137.NBCL.0049

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 2023/09/06) and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR (on the date of 2023/09/06) with the following manufacturer:

TEKNOMEK MEDIKAL MALZEME SAN. VE TIC. LTD. ŞTİ.
Karamahmet Mahallesi
Avrupa Serbest Bölgesi 9.Sk. No:14
Ergene, Tekirdağ, Türkiye
SRN Number (if available): TR-MF-000018462

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.

UDEM Adriatic d.o.o.
Address: Radnička cesta 54/R3, Green Gold Centar, 10000 Zagreb
Phone: +385 (1) 4819 601 • **Fax:** +385 (1) 4819 434
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UDEM Adriatic d.o.o.
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www.udemadriatic.com

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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

 **UDEM Adriatic d.o.o.**
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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
Ophthalmic Cannulas, Needles, Backflushes	Class IIa	N/A	Certificate 1: Production Quality Assurance System Certificate No: M.2019.106.12392 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)
DCR and Lacrimal Set	Class IIa	N/A	Certificate 1: Production Quality Assurance System Certificate No: M.2019.106.12392 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)
Ophthalmic Microsurgical Instruments, Equipment and Accessories (Eye speculum, Marker, Forceps, Chopper, Manipulator, Spatula, Rotator, Retractor, Punctal dilator, Muscle hook, Vectis, Scleral depressor, Rop set, Knives)	Class IIa	N/A	Certificate 1: Production Quality Assurance System Certificate No: M.2019.106.12392 UDEM Uluslararası Belgelendirme Denetim Eğitim 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
Medical Textile and Ophthalmic Set (Drapes, Laser Drape, Ophthalmic Set)	Class I devices placed on the market in sterile condition	N/A	Certificate 1: Production Quality Assurance System Certificate No: M.2019.106.12392 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)
Intravitreal Injection and Phaco Pack	Class IIa	N/A	Certificate 1: Production Quality Assurance System Certificate No: M.2019.106.12392 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)
Ophthalmic Gases	Class IIb implantable non-WET device	N/A	Certificate 1: Full Quality Assurance System Certificate No: M.2017.106.9081 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)
Silicone Oil	Class IIb implantable non-WET device	N/A	Certificate 1: Full Quality Assurance System Certificate No: M.2017.106.9081 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)
Tubing System- Injection and Extraction System	Class IIa	N/A	Certificate 1: Production Quality Assurance System Certificate No: M.2019.106.12392 UDEM Uluslararası Belgelendirme Denetim Eğitim 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
Perfluorodecaline	Class IIa	N/A	Certificate 1: Production Quality Assurance System Certificate No: M.2019.106.12392 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)
Ophthalmic Dyes	Class IIa	N/A	Certificate 1: Production Quality Assurance System Certificate No: M.2019.106.12392 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)
High Flow Filter and Syringe	Class IIa	N/A	Certificate 1: Production Quality Assurance System Certificate No: M.2019.106.12392 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/12/15	2023.MDR.1137.NBCL.0049	Initial Issue

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C E R T I F I C A T E

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

Company Name : Teknomek Medikal Malzemeleri Sanayi ve Ticaret Ltd. Şti.

Company Address : Halicioğlu Mah. Okumuşoğlu Sokak No:2 K:5 D:5 Beyoğlu
ISTANBUL / TURKEY

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

Product : Sterile Ophthalmic Cannulas, Needles, Backflush - Class IIa
Sterile DCR and Lacrimal Intubation set - Class IIa
Sterile Microsurgical Instruments - Class IIa
Sterile High flow filter and Syringe - Class IIa
Sterile Tubing systems-Injection and Extraction System - Class IIa
Sterile Intravitreal and Phaco kit - Class IIa
Sterile Perfluorodecaline - Class IIa
Sterile Ophthalmic dyes, (Tekno Epi Blue and Tekno Capsule Blue) - Class IIa
Sterile Ophthalmic Medical textile and Ophthalmic Set - Class Is
Sterile Eye shield - Class Is

GMDN : 12535, 15283, 35063, 35907, 45150, 45180, 46697, 46705, 46741, 46959, 47007, 47130, 47610, 47929, 59037, 62478

Certificate Number : M.2019.106.12392

Report Number : MD.3437.YB

Initial Assessment Date : 30.05.2017

Registration Date : 17.10.2019

Recertification Assessment Date : 20.12.2019

Reissue Date / No : 06.04.2020/01

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 V 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 V, section 4 of the aforementioned directive. UDEM's responsibility for class I devices covered by the EC certificate 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 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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