Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat al dispozitivelor medicale
nr. __ din 30.06.2023

Solicitantul SC "Denolga Medical" SRL, cu sediul mun. Chișinău, str. Grenoble, 149A, tel/fax: +373 22 260-602, +373 22 260-601, e-mail: olesea.cucerenco@yahoo.com,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

UI400 – ENDOFLATOR 40;

Se anexează următoarele acte:
EC-Declaration of Conformity, KARL STORZ DE & Co. KG, Germania, 2 file/ buc.
EC Quality Management System Certificate (MDR), No. G10 084462 0072 Rev.02, KARL STORZ DE & Co. KG – 4 file/ buc;
Lista dispozitivelor medicale (versiunea Excel);

Data 30.06.2023 Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **SC „Denolga Medical" SRL**, cu sediul mun. Chișinău, str. Grenoble 149A,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Sunt autentice și corespund realității.

UI400 – ENDOFLATOR 40;

Cucerenco Olesea, jurisconsult
Numele, prenumele şi funcţia *Semnătura* _____

Data 30.06.2023

Anexa nr. 3

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*	
1	UI400	ENDOFLATOR 40;	Karl Storz	UI400	16849	IIb

KARL STORZ — ENDOSKOPE

EU-Declaration of Conformity

EU-Konformitätserklärung

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.
Diese Europäische Konformitätserklärung wird in alleiniger Verantwortung des Herstellers ausgestellt.

MANUFACTURER
HERSTELLER

Name of Company ***Firmen Name***	**Address** ***Adresse***	**SRN** ***SRN***
KARL STORZ SE & Co. KG	Dr.-Karl-Storz-Str. 34 78532 Tuttlingen Germany	DE-MF-000005723

PRODUCT IDENTIFICATION
PRODUKTIDENTIFIZIERUNG

Device Description ***Produkt Bezeichnung***	**Basic UDI-DI** ***Basis UDI-DI***
Insufflator, SCB	4048551001885UV

Intended use
Zweckbestimmung

Insufflators are intended to deliver CO2 for insufflation (creating and maintaining a cavity) or replacement of ambient air in laparoscopy, thoracoscopy, transanal endoscopy and endoscopic vessel harvesting. Insufflators are non-invasive and
meant for short-term use.

REF Number(s), Short text
REF Nummer(n), Kurztext

UI400 ENDOFLATOR 40

RISK CLASS (according Annex VIII (EU) 2017/745)
RISIKOKLASSE (gemäß Anhang VIII (EU) 2017/745)

Class ***Klasse***	IIb	**Conformity Assessment Procedure** ***Konformitätsbewertungsverfahren***
Rule ***Regel***	12	Annex IX, Chapter I and III *Anhang IX, Kapitel I und III*

A complete listing of applied standards is available upon request.
Eine vollständige Liste der angewandten Normen ist auf Anfrage verfügbar.

KARL STORZ — ENDOSKOPE

EU-Declaration of Conformity

EU-Konformitätserklärung

NOTIFIED BODY
BENANNTE STELLE

Name of Company ***Firmen Name***	**Registration No** ***Registriernummer***	**Certificate Reference(s)** ***Referenz Bescheinigung(en)***
TÜV SÜD Product Service GmbH Certification Body Ridlerstraße 65 80339 Munich Germany	0123	EU Quality Management System Certificate *EU-Qualitätsmanagementbescheinigung* *G10 084462 0072*

The Manufacturer declares that the above-mentioned products meet the provision of the following EU legislation.
Der Hersteller erklärt, dass die oben genannten Produkte den Bestimmungen folgender EU-Gesetzgebung entsprechen.

(EU) 2017/745 MDR
2011/65/EU RoHS

The validity of this declaration ends with the expiration of the associated Certificate(s) latest.
Die Gültigkeit dieser Erklärung endet spätestens mit Ablauf der zugehörigen Bescheinigung(en).

Tuttlingen, 15.11.2022

KARL STORZ SE & Co. KG • Dr.-Karl-Storz-Straße 34 • 78532 Tuttlingen/Germany
STORZ KARL STORZ — ENDOSKOPE Germany

p.p. Karim Djamshidi-Gilani
Vice President (m/f/d) / Global Patient Health & R

This declaration instantly loses all validity in consequence of any product change not authorized by KARL STORZ SE & Co. KG in written form, in case of product change affects the conformity to the General Safety and Performance Requirements, so that a new placing on the market must be assumed.

Diese Erklärung verliert sofort ihre Gültigkeit in Folge jeder nicht durch KARL STORZ SE & Co. KG schriftlich autorisierten Änderung am Produkt, bei der die Konformität mit den Grundlegenden Sicherheits- und Leistungsanforderungen beeinflusst wird, so dass von einem neuen Inverkehrbringen auszugehen ist.

SAP ID: 300000583867
Version: BA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 084462 0072 Rev. 02

Manufacturer: **KARL STORZ SE & Co. KG**
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
GERMANY

SRN Manufacturer: DE-MF-000005723

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 084462 0072 Rev. 02

Report No.: 713249165

Preceding Certificate No.: G10 084462 0072 Rev. 01

Valid from: 2022-09-22
Valid until: 2025-12-17

Date of Initial Issuance: 2020-12-18

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-09-22

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 084462 0072 Rev. 02

Classification:	IIa
Device Group:	Z120202 - MOTORISED INSTRUMENTS FOR ENDOSCOPIC SURGERY
Intended Purpose:	./.

Classification:	IIa
Device Group:	Z120207 - GENITOURINARY ENDOSCOPY INSTRUMENTS
Intended Purpose:	./.

Classification:	IIa
Device Group:	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
Intended Purpose:	./.

Classification:	IIb
Device Group:	Z120203 - ENDOSCOPIC LITHOTRIPSY INSTRUMENTS
Intended Purpose:	Laser units are used to provide laser radiation for cutting, coagulation, vaporization and ablation of biological tissue, as well as for lithotripsy of stones during surgical interventions. Laser units do not come into contact with the body.

Classification:	IIb
Device Group:	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
Intended Purpose:	KARL STORZ CR1TM SCB CONTROL equipment control is used to centrally display and enable remote control of the parameters of both the SCB equipment and the designated equipment from other manufacturers which is connected to the KARL STORZ CR1 SCB CONTROL during diagnostic and therapeutic interventions. The equipment control can be operated via sterile input on touch-sensitive LCD monitors (touchscreens) and has no direct contact with the patient. The KARL STORZ CR1 SCB CONTROL hardware is used to provide a computer System in order to enable use of the KARL STORZ CR1 SCB CONTROL software. The KARL STORZ CR1 SCB CONTROL hardware has no direct contact with the patient. The KARL STORZ SCB software is used to display and enable central and sterile remote control of the parameters of both the SCB equipment connected to the KARL STORZ SCB control and the equipment from other manufacturers intended for this purpose. The KARL STORZ SCB software has no direct contact with the patient. The SCB PC card is used as a master node (administration) in the KARL STORZ SCB bus and thus enables the KARL STORZ CR1 SCB control software to control and visualize the SCB equipment. Furthermore, the SCB PC card is used as an independent watchdog for the SCB Security Task. The SCB PC card has no direct contact with the patient.

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 084462 0072 Rev. 02

Classification:	IIb
Device Group:	Z120203 - ENDOSCOPIC LITHOTRIPSY INSTRUMENTS
Intended Purpose:	CALCUSPLIT probes are intended to guide pneumatic puise energy tor lithotripsy to the caiculus. Probes are surgically invasive and meant tor short term use.
Classification:	IIb
Device Group:	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
Intended Purpose:	Insuffiators with heating are intended to dehiver and heat C02 for insuiflation (creating and maintaining a cavity) or replacement of ambient air in aparoscopy, thoracoscopy, transanal endoscopy and endoscopic vessel harvesting. Insuffiators are non-invasive and meant tor short-term use.
Classification:	IIb
Device Group:	Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY
Intended Purpose:	Suction/irrigation pumps are intended to irrigate irrigation fluid into organs, joints and on fields of intervention, as weil as to suction off irrigation and body fluids, secretions, tissue and gases. Suctionhirrigation pumps do not have body contact.
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

Revision History:

Rev.	Dated	Report
00	2020-12-18	713169106
01	2022-04-14	713224270

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ZLG-BS-244.10.08

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 084462 0012 Rev. 01

Manufacturer:

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
GERMANY

Product Category(ies):

- Light Sources
- Light Carrier (adaptable)
- Optics (Telescopes) with channel
- Optics (Telescopes) without channel
- Fiberscopes with channel
- Fiberscopes without channel
- Semiflexible endoscopes with channel
- Semiflexible endoscopes without channel
- Rigid Videoscopes with channel
- Rigid Videoscopes without channel
- Flexible Videoscopes with channel
- Flexible Videoscopes without channel
- Sheaths
- Trocars
- Instruments with movable jaws
- Instruments without movable jaws
- Working Elements/ Working Inserts
- Cannulas
- HF Instruments with movable jaws
- HF Instruments without movable jaws/ HF Electrodes
- HF Suction/ Irrigation Instruments
- HF Generators
- HF Foot Switches
- HF Working Elements
- Nonactive implants for ENT
- Nonactive bone implants for arthroscopic procedures
- Insufflators with Accessories
- Tubing Sets Insufflators
- Laser Devices
- Foot Switch Laser
- Laser Fibers
- Lithotripsy Devices
- Foot Switches Lithotripsy Devices
- Lithotripsy Probes
- Pumps
- Suction/ Irrigation Instruments
- Foot Switches with Pumps
- Tubing Sets Pumps
- Motor Control Unit
- Handpieces/ Motors

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TÜV SÜD 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 084462 0012 Rev. 01

Product Category(ies):

- Foot Switches Motor Control Unit
- Shaver/ Drills
- Morcellator Systems
- EM Navigation
- Active controlling systems, components of software

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 084462 0012 Rev. 01

Report No.: 713202293

Valid from: 2021-05-25
Valid until: 2023-07-16

Date, 2021-05-25

Christoph Dicks
Head of Certification/Notified Body

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

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