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

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

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

Se anexează următoarele acte:

Conform anexei Excel

Scrisoare confirmativă privind EC Certificate, KARL STORZ DE & Co. KG, Germania – 4 file;

EC-Declaration of Conformity, KARL STORZ DE & Co. KG, Germania, 1 file/ buc.

EC Certificate Full Quality Assurance System, Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb, III), KARL STORZ DE & Co. KG – 2 file/ buc;

Lista dispozitivelor medicale (versiunea Excel);

Data __.__.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	Digitally signed by Gherman Irina Date: 2023.11.24 15:25:09 EET Reason: MoldSign Signature Location: Moldova
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 deţin 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:

Conform anexei Excel

Sunt autentice și corespund realității.

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

Data __.__.2023

Product Service

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH • Ridlerstraße 65 • 80339 Munich • Germany

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

Munich, 2023-06-29
Order No.: 713300646_2

Confirmation concerning EC Certificate G1 084462 0012 Rev. 01 and G2S 084462 0013 Rev. 01

We confirm that the following certificates:

G1 084462 0012 Rev. 01 (valid until 2023-07-16)
G2S 084462 0013 Rev. 01 (valid until 2023-07-16)

issued to the legal medical device manufacturer:

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

cover the Directive 93/42/EEC on Medical Devices with the scope:

G1 084462 0012 Rev. 01:

- Light Sources
- Light Carrier (adaptable)
- Optics (Telescopes) with channel
- Optics (Telescopes) without channel
- Fiberscopes with channel
- Fiberscopes without channel
- Semiflexible endoscopes with 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

Product Service

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

G2S 084462 0013 Rev. 01

- Medical equipment drape
- Suction/irrigation tubing
- ENT probe
- Adhesive bandage
- Laparoscopic cholangiography catheter
- Surgical plume evacuation system filter
- Laparoscopic access cannula seal
- Surgical instrument assist arm system, manually-adjusted
- Surgical irrigation/aspiration tubing set

and the following devices:

see:
order number 713300646_2:
Attachment 1 _Devices covered by G1 084462 0012 Rev. 01
Attachment 2 _Devices covered by G2S 084462 0013 Rev. 01

Product Service

With this letter we confirm that the above-mentioned devices are covered by a quality assurance system that has been established by the manufacturer and is certified by the notified body TÜV SÜD Product Service GmbH.

After issuing the declaration of conformity in accordance with the medical device directive 93/42/EEC by the manufacturer, the above mentioned medical devices can be labelled with CE mark (CE 0123) and placed on the market in the European Economic Area.

In accordance with Article 120 (2) Regulation (EU) 2017/745 (as amended by Regulation (EU) 2023/607 – hereafter referred to as MDR) the above-mentioned certificate remains valid after the end of the period indicated on the certificate at the latest until the date set out in Article 120 (3a) MDR applicable for the relevant risk class of the devices and subject to the manufacturer's compliance with the conditions specified in Article 120 (3c) MDR.

Especially no later than **26 May 2024**, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

According to Article 120 (3a) MDR Devices which have a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until the following dates:
(a) 31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;
(b) 31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.

The above-mentioned certificates are valid.

MÜNCHEN TÜV SÜD PRODUCT SERVICE

Georg Bauer
TÜV SÜD PRODUCT SERVICE GMBH
PS-MHS-FA-0
Foreign Affairs

Article Number	Device Name	MDD classification
12063C	Oesophagoskop, für Jugendliche	IIa
12063D	Oesophagoskop, für Kinder	IIa
12063F	Oesophagoskop für Säuglinge	IIa
12063H	Oesophagoskop für Neugeborene	IIa
12064A	Oesoph.Spekulum,24 cm, 35 x 22 mm	IIa
12064B	Oesoph.Spekulum,23 cm, 29 x 18 mm	IIa
12067A	Spreiz-Divertikuloskop	IIa
12067B	Spreiz-Divertikuloskop	IIa
12067M	Rauchabsaugrohr	IIa
12067P	Koag. Saugrohr, 3,5 mm, 30 cm	IIb
12067R	Saugrohr, isoliert 30 cm, 2.5 mm	IIa
12067S	Saugrohr, isoliert 30 cm, 3 mm	IIa
12068A	Doppelschnabel-Divertikuloskop	IIa
12068B	Doppelschnabel-Divertikuloskop	IIa
1215AA	Tele-Otoskop, mit Optik 0°, Ø 4 mm, 6cm	IIa
1216AA	HOPKINS Optik 0°, Ø 4 mm, 11 cm	IIa
1216BA	HOPKINS Optik 30°, Ø 4 mm, 11 cm	IIa
1216CA	HOPKINS Optik 70°, Ø 4 mm, 11 cm	IIa
1218AA	Tele-Otoskop 0°, Ø 3 mm, 6 cm	IIa
1218AL	Schaft f. LASER-Sonde u.1218 A/AA	IIa
1218BA	Tele-Otoskop 30°, Ø 3 mm, 6 cm	IIa
1218BL	Schaft f. LASER-Sonde u.1218 B/BA	IIa
1218CA	Tele-Otoskop, mit Optik 70°, Ø 3 mm, 6cm	IIa
1218FA	Tele-Otoskop, mit Optik 45°, Ø 3 mm, 6cm	IIa
1230AA	HOPKINS Optik 0°, Ø 2,7 mm, 11 cm	IIa
1230BA	HOPKINS Optik 30°, Ø 2,7 mm, 11 cm	IIa
1230CA	HOPKINS Optik 70°, Ø 2,7 mm, 11 cm	IIa
1232AA	HOPKINS Optik 0°, Ø 1,9 mm, 10 cm	IIa
1232BA	HOPKINS Optik 30°, Ø 1,9 mm, 10 cm	IIa

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
ZLG-BS-244.10.08

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

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

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

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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
ZLG-BS-244.10.08

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

KARL STORZ — ENDOSKOPE

EC-DECLARATION OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG

Device Name Produkt Name	HOPKINS® Telescope 0°, Ø 2.7 mm, 11 cm
Model Number(s) Modell Nummer(n)	1230AA
Classification Klassifizierung	Class IIa per Annex IX, Rule 7 of Council Directive 93/42/EEC Klasse IIa gemäß Anhang IX, Regel 7 der Richtlinie 93/42/EWG des Rates

We issue the present Declaration of Conformity on our sole responsibility and herewith declare self-dependent that the device mentioned above meets the Essential Requirements as defined in Annex I MDD 93/42/EEC .
Wir stellen die vorliegend Konformitätserklärung in Eigenverantwortung aus und erklären hiermit unter alleiniger Verantwortung, dass das oben genannte Produkt die Grundlegenden Anforderungen gemäß Anhang I MDD 93/42/EWG erfüllt.

This Declaration of Conformity is issued according to Annex II excluding (4) Council Directive 93/42/EEC for Medical Devices (for class IIa and IIb devices).
Diese Konformitätserklärung ist erstellt gemäß Anhang II ohne Abschnitt (4) Richtlinie 93/42/EWG des Rates über Medizinprodukte (für Klasse IIa und IIb Produkte).
Notified Body / Registration Number / Benannte Stelle / Registrierungsnummer:
TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München / 0123

Full list of applied standards, directives and laws (12-C2.3.F013-LOAS-CM005) on request.
Vollständige Liste angewandter Normen, Richtlinien und Gesetze (12-C2.3.F013-LOAS-CM005) auf Anfrage.

The validity of this declaration is determined by EC certificate number: G1 18 04 84462 012
Die Gültigkeit dieser Erklärung bestimmt sich nach dem EG Zertifikat mit der Nummer: G1 18 04 84462 012

CE 0123

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

Tuttlingen, 17 Juli 2018

i. V. Serkan Sezer
Vice President
Global Quality Management,
Regulatory Affairs, RSB & Service

This declaration loses all validity if KARL STORZ SE & Co. KG performs a product change which affects the Conformance to the Essential Requirements or an alteration of any kind not approved by KARL STORZ SE & Co. KG was made at the device mentioned above.
Diese Erklärung verliert ihre Gültigkeit sobald KARL STORZ SE & Co. KG Produktänderungen durchführt, welche die Konformität mit den Grundlegenden Anforderungen beeinflusst oder eine Änderung jeglicher Art ohne Freigabe durch die KARL STORZ SE & Co. KG am oben genannten Produkt durchgeführt wird.

Anexa nr. 3

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*	
1	1230AA	HOPKINS® Telescope 0°, Ø 2.7 mm, 11 cm	Karl Storz	1230AA	12291	IIa