

Către Agenția Medicamentului
și 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 și tipuri de dispozitive medicale pentru introducerea și punerea la
dispoziție pe piață a:

Se anexează următoarele acte:

26174BN – SUCTION AND IRRIGATION TUBE, 43 CM
37360CP – SUCTION A. IRRIG. CANNULA, L. 36 CM
33400 – METAL OUTER SHEATH, INSULATED, 43 CM
38700 – RoBi METAL OUTER SHEATH
30107H2 – CANNULA, WITHOUT VALVE, SIZE 13 MM

Scrisoare confirmativă privind EC Certificate, KARL STORZ DE & Co. KG,
Germania – 3 file;

EC-Declaration of Conformity, KARL STORZ DE & Co. KG, Germania, 5 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 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	

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

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

declar pe proprie răspundere, cunoscând prevederile art. **352¹**, Codul
Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și
datele furnizate pentru notificarea dispozitivului medical:

26174BN – SUCTION AND IRRIGATION TUBE, 43 CM

37360CP – SUCTION A. IRRIG. CANNULA, L. 36 CM

33400 – METAL OUTER SHEATH, INSULATED, 43 CM

38700 – RoBi METAL OUTER SHEATH

30107H2 – CANNULA, WITHOUT VALVE, SIZE 13 MM

Sunt autentice și corespund realității.

Cucerenco Olesea, juriconsult

Numele, prenumele și funcția

Semnătura

Data 30.06.2023

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*	
1	26174BN	SUCTION AND IRRIGATION TUBE, 43 CM	Karl Storz	26174BN	16779	Ila
2	37360CP	SUCTION A. IRRIG. CANNULA, L. 36 CM	Karl Storz	37360CP	16779	Ila
3	33400	METAL OUTER SHEATH, INSULATED, 43 CM	Karl Storz	33400	35080	Ila
4	38700	RoBi METAL OUTER SHEATH	Karl Storz	38700	32684	Ila
5	30107H2	CANNULA, WITHOUT VALVE, SIZE 13 MM	Karl Storz	30107H2	37148	Ila



Product Service

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

**Add value.
Inspire trust.**

To whom it may concern

Munich, 2021-07-08

Order No.: 713218192

Confirmation concerning EC Certificates G1 084462 0012 Rev. 01, G1 18 04 84462 012, G2S 084462 0013 Rev. 01 and G2S 18 04 84462 013 and

We confirm that the following certificates:

G1 084462 0012 Rev. 01 (issued on 2021-05-25; valid until 2023-07-16)
G2S 084462 0013 Rev. 01 (issued on 2021-05-25; valid until 2023-07-16)

issued to the legal manufacturer of medical devices:

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

cover the Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) with the product categories (**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
- 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

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at www.tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)

Board of Management:
Walter Reithmaier (CEO)
Dr. Jens Butenandt (CTO)
Patrick van Welij (CFO)

Phone: +49 89 5008-4493
Fax: +49 89 5008-4108

www.tuvsud.com/ps



TÜV SÜD Product Service GmbH
Foreign Affairs
Ridlerstrasse 65
80339 Munich
Germany



- 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

cover the Directive 93/42/EEC on Medical Devices (MDD), Annex V with the product categories
(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

With this letter we confirm that the products covered by the certificate **G1 084462 0012 Rev. 01** and **G2S 084462 0013 Rev. 01** are identical with the products covered by certificate **G1 18 04 84462 012** and **G2S 18 04 84462 013**, respectively (certificate replaced).

We further 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.

The above-mentioned medical devices can be labelled with CE mark (CE 0123) and placed on the market in the European Economic Area based on the existing declaration of conformity issued by the



Product Service

manufacturer before 2021-05-26 in accordance with the medical device directive 93/42/EEC with the certificate number G1 18 04 84462 012 or G2S 18 04 84462 013. The certificate ID changed due to modification of the internal enumeration system.

The above-mentioned certificates are valid.

R. Köhler

Randolf Köhler
TÜV SÜD PRODUCT SERVICE GMBH
Medical Health Services
Foreign Affairs





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



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:G10844620012Rev.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

EC-DECLARATION OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG

Device Name Produkt Name	Suction and Irrigation Tube, 43 cm
Model Number(s) Modell Nummer(n)	26174BN
Classification Klassifizierung	Class IIa per Annex IX, Rule 6 of Council Directive 93/42/EEC Klasse IIa gemäß Anhang IX, Regel 6 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 vorliegende 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-CM001) on request.
Vollständige Liste angewandter Normen, Richtlinien und Gesetze (12-C2.3.F013-LOAS-CM001) 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



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.

EC-DECLARATION OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG

Device Name Produkt Name	Suction a. Irrig. Cannula, L. 36cm
Model Number(s) Modell Nummer(n)	37360CP
Classification Klassifizierung	Class IIa per Annex IX, Rule 6 of Council Directive 93/42/EEC Klasse IIa gemäß Anhang IX, Regel 6 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 vorliegende 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-CM001) on request.
Vollständige Liste angewandter Normen, Richtlinien und Gesetze (12-C2.3.F013-LOAS-CM001) 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



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.

EC-DECLARATION OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG

Device Name Produkt Name	Metal Outer Sheath, insulated, 43 cm
Model Number(s) Modell Nummer(n)	33400
Classification Klassifizierung	Class IIa per Annex IX, Rule 6 of Council Directive 93/42/EEC Klasse IIa gemäß Anhang IX, Regel 6 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 vorliegende 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-CM002) on request.
Vollständige Liste angewandter Normen, Richtlinien und Gesetze (12-C2.3.F013-LOAS-CM002) 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



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.

EC-DECLARATION OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG

Device Name Produkt Name	RoBi® Metal Outer Sheath
Model Number(s) Modell Nummer(n)	38700
Classification Klassifizierung	Class IIa per Annex IX, Rule 6 of Council Directive 93/42/EEC Klasse IIa gemäß Anhang IX, Regel 6 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 vorliegende 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 (ZA001) on request.
Vollständige Liste angewandter Normen, Richtlinien und Gesetze (ZA001) 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



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.

EC-DECLARATION OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG

Device Name Produkt Name	Cannula, without valve, size 13 mm
Model Number(s) Modell Nummer(n)	30107H2
Classification Klassifizierung	Class IIa per Annex IX, Rule 6 of Council Directive 93/42/EEC Klasse IIa gemäß Anhang IX, Regel 6 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 vorliegende 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-CM003) on request.
Vollständige Liste angewandter Normen, Richtlinien und Gesetze (12-C2.3.F013-LOAS-CM003) 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



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.