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 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:

26778UE – COAGULATING ELECTRODE, L.43 CM
34410MA – CLICKLINE SCISSORS INSERT
38710MD – RoBi KELLY FORCEPS INSERT
33310AA – CLICKLINE FORCEPS INSERT

Se anexează următoarele acte:
Scrisoare confirmativă privind EC Certificate, KARL STORZ DE & Co. KG, Germania – 3 file;
EC-Declaration of Conformity, KARL STORZ DE & Co. KG, Germania, 4 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 – 1 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)	Digitally signed by Gherman Irina Date: 2023.07.03 11:25:29 EEST Reason: MoldSign Signature Location: Moldova
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:

Sunt autentice și corespund realității.

26778UE – COAGULATING ELECTRODE, L.43 CM

34410MA – CLICKLINE SCISSORS INSERT

38710MD – RoBi KELLY FORCEPS INSERT

33310AA – CLICKLINE FORCEPS INSERT

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	26778UE	COAGULATING ELECTRODE, L.43 CM	Karl Storz	26778UE	38816	IIb
2	34410MA	CLICKLINE SCISSORS INSERT	Karl Storz	34410MA	46421	IIb
3	38710MD	RoBi KELLY FORCEPS INSERT	Karl Storz	38710MD	32684	IIb
4	33310AA	CLICKLINE FORCEPS INSERT	Karl Storz	33310AA	35080	IIb

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

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

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

TÜV®

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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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

.

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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KARL STORZ — ENDOSKOPE

EC-DECLARATION OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG

Device Name Produkt Name	Coagulating Electrode, l. 43 cm
Model Number(s) Modell Nummer(n)	26778UE
Classification Klassifizierung	Class IIb per Annex IX, Rule 9 of Council Directive 93/42/EEC Klasse IIb gemäß Anhang IX, Regel 9 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-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

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.

KARL STORZ — ENDOSKOPE

EC-DECLARATION OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG

Device Name Produkt Name	CLICKLINE Scissors Insert
Model Number(s) Modell Nummer(n)	34410MA
Classification Klassifizierung	Class IIb per Annex IX, Rule 9 of Council Directive 93/42/EEC Klasse IIb gemäß Anhang IX, Regel 9 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-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

CE 0123

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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.

KARL STORZ — ENDOSKOPE

EC-DECLARATION OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG

Device Name Produkt Name	RoBi® KELLY Forceps Insert
Model Number(s) Modell Nummer(n)	38710MD
Classification Klassifizierung	Class IIb per Annex IX, Rule 9 of Council Directive 93/42/EEC Klasse IIb gemäß Anhang IX, Regel 9 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 (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

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.

KARL STORZ — ENDOSKOPE

EC-DECLARATION OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG

Device Name Produkt Name	CLICKLINE Forceps Insert
Model Number(s) Modell Nummer(n)	33310AA
Classification Klassifizierung	Class IIb per Annex IX, Rule 9 of Council Directive 93/42/EEC Klasse IIb gemäß Anhang IX, Regel 9 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-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

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

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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.

Product Service

Add value.
Inspire trust.

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

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

Product Service

- 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

MÜNCHEN

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