Digitally signed by Bunic Gheorghe
Date: 2022.12.04 10:24:58 EET
Reason: MoldSign Signature
Location: Moldova

CERTIFICATE

EC Certificate No. 1434-MDD-420/2021

Full Quality Assurance System
Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Soluscope SAS

100 rue du Fauge
ZI Les Paluds
Aubagne 13400 FRANCE

for the design, manufacture and final inspection of
medical devices, class IIb

Washer-disinfectors for endoscopes or TEE probes and disinfectant solutions

The list of medical devices covered by this certificate is provided in the annex 1

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 25.05.2021 to 26.05.2024

The date of issue of the Certificate: 25.05.2021

The date of the first issue of the Certificate: 26.04.2019

CE 1434

Issued under the Contract No. MD-15/2020, MD-33/2021
Application No: 642/2020, 520/2021
Certificate bears the authorized person signature.
Warsaw, 25/05/2021
Module H2/3/4/5

FBM-26-E_9

Vice-President

Polish Centre for Testing and Certification 469 Puławska Street, 02-844 Warsaw Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

MED CERT®

Certification. Medical Only.

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

MTW - Endoskopie W. Haag KG
Goldsbergstr. 18
46487 Wesel
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

Effective date: **2020-06-23**
Expiry date: **2023-07-01**

Report No.: 1484PS23F
Process No.: QS – 1484
Certificate No.: 1484GB410200623

Hamburg, 2020-06-23

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

MED CERT®

Certification. Medical Only.

Appendix of EC Certificate of Conformity

Process No.: QS – 1484
Certificate No.: 1484GB410200623

List of locations included in the scope of certificate

Sebastianusstr. 33
46487 Wesel
Germany

Sebastianusstr. 35
46487 Wesel
Germany

Sebastianusstr. 52
46487 Wesel
Germany

Weseler Straße 96
46487 Wesel
Germany

– End of list –

MED CERT®

Certification. Medical Only.

Appendix of EC Certificate of Conformity

Process No.: QS – 1484
Certificate No.: 1484GB410200623

List of products / product categories included in the scope of certificate

- **Aspiration Needles**
- **Balloon Catheters**
- **Baskets for foreign bodies**
- **Biopsy Cannulas**
- **Biopsy Forceps**
- **Check Valves**
- **Coagulation Probes**
- **Cyst Drainage Enlarger Sets (Stents, Cyst; Guiding Catheters, Pushers)**
- **Cyst Drainage Sets (Stents, Cyst; Cystostomes; Pushers)**
- **Cystostomes**
- **Dilatation Catheters**
- **ESD-Knives**
- **Guide Wires**
- **HF-Knives, HF-Needles**
- **High Frequency Clamps**
- **Injection Needles**
- **Lithotomy Baskets**
- **Lithotripters**
- **Nasobiliary Drainage Catheters**
- **Papillotomes**
- **Polypectomy Snares**
- **Positioning Aids (Introducer Systems, Guiding Catheters, Pushers, Extraction Catheters, Extraction Snares)**
- **Ring Knife Sets (Stents, Cyst; Ring Knives; Pushers)**
- **Ring Knives**
- **Stents, Bile**
- **Stents, Cyst**
- **Stents, Pancreas**
- **Stent-Sets, Bile (Stents, Bile; Guiding Catheters; Pushers)**
- **Stent-Sets, Pancreas (Stents, Pancreas; Guiding Catheters; Pushers)**

– End of list –

MED CERT®

Certification. Medical Only.

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

MTW - Endoskopie W. Haag KG
Goldsbergstr. 18
46487 Wesel
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system
for the aspects of manufacture concerned with securing and maintaining sterile conditions

for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

This certification is subject to surveillance by MEDCERT.

Effective date: **2020-06-23**
Expiry date: **2023-07-01**

Report No.: 1484PS23F
Process No.: QS – 1484
Certificate No.: 1484GB415200623

Hamburg, 2020-06-23

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

MED CERT®

Certification. Medical Only.

Appendix of EC Certificate of Conformity

Process No.: QS – 1484
Certificate No.: 1484GB415200623

List of locations included in the scope of certificate

Sebastianusstr. 33
46487 Wesel
Germany

Sebastianusstr. 35
46487 Wesel
Germany

Sebastianusstr. 52
46487 Wesel
Germany

Weseler Straße 96
46487 Wesel
Germany

– End of list –

MED CERT®

Certification. Medical Only.

Appendix of EC Certificate of Conformity

Process No.: QS – 1484
Certificate No.: 1484GB415200623

List of products / product categories included in the scope of certificate

- **Antifoaming Needles**
- **Aspiration Needles**
- **Balloons for Echo Endoscopy**
- **Biopsy Cannulas**
- **Biopsy Forceps**
- **Biopsy Valves**
- **Cytology Brushes**
- **ERCP-Catheters**
- **Foreign Body Protector Hoods**
- **Foreign Body Removing Forceps**
- **Polypotomes**
- **Lithotriptors**
- **Spray Catheters**
- **Wash-Out Probe**

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

EC Certificate Full Quality Assurance System: Certificate BE19/819943763

The management system of

G-Flex Europe Sprl

Rue de l'Industrie 20
1400 Nivelles, Belgium

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Multiband Ligator, non-sterile disposable device for the treatment of oesophageal varices.
Sterile Non-Vascular Guidewires
Sterile Extraction Baskets & lithotripsy system
Sterile Disposable Hemoclip system
Sterile Disposable Biopsy Forceps

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 16 December 2019 until 01 June 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 01 April 2013
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered BE/AND 12/1285.QMD

Authorised by

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

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 106138 0002 Rev. 00

Manufacturer:

Marflow AG
Soodstrasse 57
8134 Adliswil, Zurich
SWITZERLAND

Product Category(ies):

Class IIb
Double J stent & set
Class IIa
PCN catheter & set
Ureteral catheter
Malecot catheter
Re-entry malecot catheter
Suprapubic catheter
Braided shaft catheter
Dual lumen catheter
Facial dilator
Amplatz dilator & set
Ureteral dilator & set
Ureteral balloon dilator
Double J stent & set
Mono J stent
Endopyelotomy stent
Guidewire
IP Needle
Chiba needle
Stone basket
Perk basket

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. See also notes overleaf.

Report No.: IND20190101

Valid from: 2020-04-03
Valid until: 2024-05-26

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®

Legalization see reverse side

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

A4 / 07.17

Official Certification

Seen for authentication of the foregoing signature, acknowledged in our presence by

Ms. **Tracey WALTHER**, born 28th December 1958, Swiss citizen of Oberentfelden AG, according to her information residing at Brunaustrasse 17, 8002 Zürich,
identified by identity card.

Zürich, 8th April 2020
BK no. 1027ff
Fee CHF 20.00

NOTARIAT ENGE-ZÜRICH

Andreas Bachmann, Notary Public

APOSTILLE
(Convention de la Haye du 5 octobre 1961)

1. Land: Schweizerische Eidgenossenschaft, Kanton Zürich
   Country: Swiss Confederation, Canton of Zürich
   Diese öffentliche Urkunde / This public document
2. ist unterschrieben von
   has been signed by Andreas Bachmann
3. in seiner Eigenschaft als
   acting in the capacity of Notary Public
4. sie ist versehen mit dem Stempel/Siegel des (der) – bears the stamp/seal of
   Notariat Enge–Zürich Kanton Zürich

Bestätigt / Certified

5. In / at 8090 Zürich / Zurich
6. am / the 08.04.2020
7. durch die Staatskanzlei des Kantons Zürich
   by the Chancellery of State of the Canton of Zurich
8. unter Nr. / under N° 1179274/2020
9. Stempel/Siegel, Stamp/seal
10. Unterschrift / Signature

S. Overkott

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 106138 0001 Rev. 00

Holder of Certificate: **Marflow AG**
Soodstrasse 57
8134 Adliswil, Zurich
SWITZERLAND

Facility(ies): Marflow AG
Soodstrasse 57, 8134 Adliswil, Zurich, SWITZERLAND

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Manufacture and Supply of Medical Disposables, Surgical Tools, Equipment & Accessories in the Field of Urology, Gastroenterology, Radiology, Gynaecology & Cardiology.**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: IND20190101

Valid from: 2020-04-03
Valid until: 2023-04-02

Date, 2020-04-03

Christoph Dicks
Head of Certification/Notified Body

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

Legalization see reverse side

Official Certification

Seen for authentication of the foregoing signature, acknowledged in our presence by

Ms. **Tracey WALTHER**, born 28th December 1958, Swiss citizen of Oberentfelden AG, according to her information residing at Brunaustrasse 17, 8002 Zürich,
identified by identity card.

Zürich, 8th April 2020
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Fee CHF 20.00

NOTARIAT ENGE-ZÜRICH

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S. Overkott

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 I in sterile conditions, sterilized systems or procedure packs)

No. G1S 106138 0003 Rev. 00

Manufacturer:

Marflow AG
Soodstrasse 57
8134 Adliswil, Zurich
SWITZERLAND

Product Category(ies):

Class Is
Urine bag connector
Penile clamp
Evacuator
IUI catheter without syringe

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex II. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: IND20190101

Valid from: 2020-04-03
Valid until: 2024-05-26

Date, 2020-04-03

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

Legalization see reverse side

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

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   Notariat Enge – Zürich Kanton Zürich

Bestätigt / Certified
5. In / at 8090 Zürich / Zurich
6. am / the 08.04.2020
7. durch die Staatskanzlei des Kantons Zürich
   by the Chancellery of State of the Canton of Zurich
8. unter Nr. / under N° 1179273/2020
9. Stempel/Siegel, Stamp/seal
10. Unterschrift / Signature

S. Overkott

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÈQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod lisem 129/2, 171 02 Praha 8 - Troja

EC CERTIFICATE
FULL QUALITY ASSURANCE SYSTEM

issued in accordance with Annex 2 of Government Order No. 54/2015 Coll.
(Annex II of Directive 93/42/EEC)

No.: MED 210018

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer **ELLA-CS, s.r.o.**
Milady Horákové 504/45, Třebeš, 500 06 Hradec Králové, Czech Republic

for design, manufacturing and final inspection of medical device(s)

Stents with delivery systems for gastrointestinal tract - class IIb, see enclosure

meets the provisions of Annex 2 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex II of Directive 93/42/EEC). The certificate does not cover examination of the medical device design in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 6 of Government Order No. 54/2015 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. **MED000176-03/01 of: 18.05.2021,**

MED000176-04/01 of: 18.05.2021.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 2 clause 11 of Government Order No. 54/2015 Coll. (Annex II clause 5 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

For class III medical devices this certificate can be used only with EC Design-Examination Certificate issued in accordance with Annex 2 clause 8 of Government Order 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from 20.05.2021 with validity until 26.05.2024
The validity of this Certificate is limited until: 26.05.2024

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja

20.05.2021

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

Stamp

CER/MED210018

Certificate history

Date	Status	Reason
20.05.2021	Issuance	Replacement of certificate No. MED 170034

Stents with delivery systems for gastrointestinal tract, class IIb

Esophageal Stent Danis Seal (Danis Seal*)
FerX-ELLA Esophageal Stent (Boubella*)
FerX-ELLA Esophageal Stent (Boubella-E*)
SX-ELLA Stent Colorectal (Enterella*)
SX-ELLA Stent Pyloroduodenal (Enterella*)
SX-ELLA Stent Esophageal (Flexella Plus*) PUSH

End of list

elektrotechnický zkušební ústav
ezú
Pod lisem 129/2, 171 02 Praha 8 - Troja
-1-

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
256415-2018-AQ-FIN-FINAS

Initial certification date:
05 June 1997

Valid:
01 March 2021 – 29 February 2024

This is to certify that the management system of

Biohit Oyj

Laippatie 1, FI-00880 Helsinki, Finland

has been found to conform to the Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope:

Design/development, manufacture, marketing, and sales/distribution of in vitro diagnostic medical devices, including near-patient tests, and acetaldehyde binding medical devices used in the diagnosis and/or management of gastrointestinal diseases, risk of cancer, and different health statuses/disorders.
Design/development, manufacture, marketing, and sales/distribution of biological raw materials for the research and diagnostic markets.

Place and date:
Espoo, 04 February 2021

For the issuing office:
DNV GL - Business Assurance
Keilaranta 1, 02150 Espoo, Finland

Kimmo Haarala
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.
ACCREDITED UNIT: DNV GL Business Assurance Finland Oy Ab, Keilaranta 1, 02150 Espoo, Finland - TEL: +358 10 292 4200. www.dnvgl.fi/assurance

EC CERTIFICATE

Full Quality Assurance System

Certificate No.: 248064-2017-CE-KOR-NA-PS Rev. 6.0 Project No.: PRJC-551628-2016-MSL-KOR Valid Until: 28 May 2023

This is to certify that the quality system of:

FINEMEDIX CO., LTD.

140-9, Yuram-ro, Dong-gu, Daegu, 41059, Republic of Korea

For design, production and final product inspection/testing of:

Endoscopic electric devices and Endoscopic non-electric devices

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 21 April 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Eugenie Winger Husebye
Technical Reviewer

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	28 May 2019
1.0	Scope Extension_model added	04 December 2018
2.0	Product Name changed	18 February 2019
3.0	Scope Extension_model added	02 December 2019
4.0	Editorial change	17 December 2019
5.0	Scope Extension_model added	30 January 2020
6.0	**Site relocation**	**21 April 2021**

Products covered by this Certificate:

Product Description	Product Name	Class
Endoscopic electric devices	ClearCut Knife	IIb
	ClearGrasp Snare	
	ClearCoajet	
	FineTome	
	ClearHemograsper	
	Clear-Hemostat	
	Clear-CoaBite	
Endoscopic non-electric devices	Clear-Jet Injection Catheter	IIa
	Clear-Bite Biopsy Forceps	
	Clear-Retriever	
	ClearTip	
	ClearEndoclip	
	Fine-Grab Basket	
Endoscopic non-electric devices	ClearCap Distal Attachment	Is

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
FINEMEDIX CO., LTD.	140-9, Yuram-ro, Dong-gu, Daegu, 41059, Republic of Korea

EU Representative

Medical Device Safety Service GmbH, Schiffgraben 41, 30175 Hannover, Germany

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:	Initial certification date:	Valid:
256415-2018-AQ-FIN-FINAS	05 June 1997	01 March 2021 – 29 February 2024

This is to certify that the management system of

Biohit Oyj

Laippatie 1, FI-00880 Helsinki, Finland

has been found to conform to the Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope:

Design/development, manufacture, marketing, and sales/distribution of in vitro diagnostic medical devices, including near-patient tests, and acetaldehyde binding medical devices used in the diagnosis and/or management of gastrointestinal diseases, risk of cancer, and different health statuses/disorders.
Design/development, manufacture, marketing, and sales/distribution of biological raw materials for the research and diagnostic markets.

Place and date:
Espoo. 04 February 2021

FINAS
Finnish Accreditation Service
S001 (EN ISO/IEC 17021)

For the issuing office:
DNV GL - Business Assurance
Kellaranta 1, 02150 Espoo, Finland

Kimmo Haarala
Management Representative

DocuSign Envelope ID: [illegible]

ATTESTATION / *CERTIFICATE* N° 7752 rev. 13
Délivrée à Paris le 07 mai 2020
Issued in Paris on May 7th, 2020

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

LAMIDEY NOURY MEDICAL
3 Rue des Petits Ruisseaux ZA les Godets
91370 Verrières-le-Buisson FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category*

- Appareils d'électrochirurgie à courant haute fréquence et leurs accessoires stériles et non stériles
- Appareils d'aspiration médicale et leurs accessoires

- High frequency surgical equipments and sterile and not sterile accessories
- Medical and surgical suction equipment and accessories

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P600666 / P601472-2, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P600666 / P601472-2, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date :* **May 7th, 2020 (included)**
Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

DocuSigned by:
Béatrice Lys

On behalf of the President
Béatrice LYS
Technical Director

GMED - 7752 rev. 13
Modifie le certificat 7752-12