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

Digitally signed by Bunic Gheorghe
Date: 2024.04.21 17:26:02 EEST
Reason: MoldSign Signature
Location: Moldova

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

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

TÜV SÜD
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

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

A4 / 07.17

Official Certification

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S. Overkott

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 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

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Legalization see reverse side

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

NOTARIAT ENGE-ZÜRICH

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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

MED000176-03

Certificate history

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

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

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-

Agenţia Naţională pentru Sănătatea Publică

CERTIFICAT
DE ÎNREGISTRARE DE STAT/AVIZARE SANITARĂ
AL PRODUSULUI BIOCID

Nr. **00041** data/luna/anul **15.06.2020**

Solicitant: For titular **SRL „SOFRAGRUP"- SRL.**

Adresa juridică: ***str. Nicolae H. Costin 65/3,ap.56, mun. Chişinău, Republica Moldova***
Nr. de identificare de stat – codul fiscal 1007600073921

În conformitate cu HG nr. 546 din 10.09.09 şi în baza ordinului ANSP **nr. 71 din 15.06.2020**
(nr., data/luna/anul)

emis în baza documentaţiei înaintate, s-a decis că următorul produs biocid poate fi fabricat sau **comercializat şi utilizat** în Republica Moldova, conform prevederilor legislaţiei în vigoare.

Denumirea comercială a produsului: **PHAGO'SPORE, PHAGO' WIPES SPORE**

1. Date de identificare ale produsului:

1.1 Categoria de produs: **biocid**

- ***Grupa principală:*** **1**
- ***Tip de produs:*** **2, 4**

1.2 Utilizare: **Dezinfectarea şi curăţarea suprafeţelor şi dispozitivelor medicale non - invazive.**

1.3 Forma de condiţionare şi ambalare: ***lichid şi şervetele albe (200x200 mm).***

1.4 Conţinut în substanţe active: Peroxid de hidrogen – 3,5 %

1.5 Categorii de utilizatori: **profesionali.**

1.6 Informaţii privind reglementările aplicabile: **HG nr. 564 din 10.09.2009, Ordinul MS nr.299 din 06.05.2010 cu modificările ulterioare.**

2. Date de identificare ale producătorului:

2.1 Firma: **Christeyns France SA**

2.2 Adresa: **3l rue de la Maladrie PI de la Vertonne – 44120 VERTOU, Franţa.**

Valabilitatea certificatului de înregistrare data/luna/anul **15.06.2025**

Compoziţia, parametrii de calitate ai produsului şi domeniul de utilizare sunt cei prevăzuţi în documentaţia tehnică, care a stat la baza eliberării prezentului certificat, conform Raportului de evaluare nr. **45** din **05.06.2020.**

Orice modificare a datelor de identificare a produsului biocid, duce în mod automat la anularea certificatului de înregistrare.

Director **Nicolae FURTUNĂ**

Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Stent application system
Basic UDI-DI:	54200513-TF01-PSH-SU-GP
Classification:	Class Is, Rule 5
Conformity assessment route:	MDD Annex II Excluding Article 4
Models:	See attachment

G-Flex Europe SPRL declares on our own responsibility that the medical device describe above are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) as amended by Directive 2007/47/EC and of its transpositions in national laws and are in conformity with the relevant harmonized standards EN 1041:2008/A1:2013; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999; ASTM F1980-16; EN 556-1:2001; EN ISO 10993-7:2008; EN ISO 11607-1:2017; EN ISO 11607-2:2017; EN ISO 11737-2:2009; EN ISO 14644-1:2015; EN ISO 14644-2:2015; ISO 11135:2014; ISO 11138-1:2017; ISO 11138-2:2017; ISO 11737-1:2018; ISO 80369-7:2016.

This statement of conformity is only valid in connection with a signed Delivery Note for the respective Lot number of produced devices.

The device fulfill the essential requirements of Annex I of the MDD.

Notify Body:	SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp - Belgium
NB identification number:	1639
Expiry Date:	01/jun/2023
Place and date of issue:	Nivelles, 24/03/2022

Thierry CREMER - Quality Manager

G-Flex Europe SPRL - Simple & Performing
VAT: BE0876.308.490 Certified ISO 13485

Declaration of Conformity

Attachment

Product Name: Stent application system

Basic UDI-DI: 54200513-TF01-PSH-SU-GP

Reference	UDI-DI	GMDN	GMDN Term
DISS05U	5420051302932	61528	Endoscopic stent-placement catheter
DISS08U	5420051300600	61528	Endoscopic stent-placement catheter

Reference	UDI-DI	GMDN	GMDN Term
DISS07U	5420051300587	61528	Endoscopic stent-placement catheter
DISS10U	5420051300624	61528	Endoscopic stent-placement catheter

Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Endoscopic drainage Stent & Application system
Basic UDI-DI:	54200513-TF01-STT-SU-NT
Classification:	Class IIb, Rule 8
Conformity assessment route:	MDD Annex II Excluding Article 4
Models:	See attachment

G-Flex Europe SPRL declares on our own responsibility that the medical device describe above are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) as amended by Directive 2007/47/EC and of its transpositions in national laws and are in conformity with the relevant harmonized standards EN 1041:2008/A1:2013; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999; ASTM F1980-16; EN 556-1:2001; EN ISO 10993-7:2008; EN ISO 11607-1:2017; EN ISO 11607-2:2017; EN ISO 11737-2:2009; EN ISO 14644-1:2015; EN ISO 14644-2:2015; ISO 11135:2014; ISO 11138-1:2017; ISO 11138-2:2017; ISO 11737-1:2018.

This statement of conformity is only valid in connection with a signed Delivery Note for the respective Lot number of produced devices.

The device fulfill the essential requirements of Annex I of the MDD.

Notify Body:	SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp - Belgium
NB identification number:	1639
Expiry Date:	01/jun/2023
Place and date of issue:	Nivelles, 24/03/2022

Thierry CREMER - Quality Manager

G-Flex Europe SPRL - Simple & Performing
VAT: BE0876.308.490 Certified ISO 13485

Declaration of Conformity

Attachment

Product Name: Endoscopic drainage Stent & Application system

Basic UDI-DI: 54200513-TF01-STT-SU-NT

Reference	UDI-DI	GMDN	GMDN Term
B0705	5420051300358	43764	Polymeric biliary stent, non-bioabsorbable
B0707	5420051300365	43764	Polymeric biliary stent, non-bioabsorbable
B0709	5420051300372	43764	Polymeric biliary stent, non-bioabsorbable
B0712	5420051300389	43764	Polymeric biliary stent, non-bioabsorbable
B0715	5420051300396	43764	Polymeric biliary stent, non-bioabsorbable
B0805	5420051300402	43764	Polymeric biliary stent, non-bioabsorbable
B0807	5420051300419	43764	Polymeric biliary stent, non-bioabsorbable
B0809	5420051300426	43764	Polymeric biliary stent, non-bioabsorbable
B0812	5420051300433	43764	Polymeric biliary stent, non-bioabsorbable
B0815	5420051300440	43764	Polymeric biliary stent, non-bioabsorbable
B1005	5420051300457	43764	Polymeric biliary stent, non-bioabsorbable
B1007	5420051300464	43764	Polymeric biliary stent, non-bioabsorbable
B1008	5420051307241	43764	Polymeric biliary stent, non-bioabsorbable
B1009-ST	5420051303786	43764	Polymeric biliary stent, non-bioabsorbable
B1011	5420051307265	43764	Polymeric biliary stent, non-bioabsorbable
B1012-ST	5420051303557	43764	Polymeric biliary stent, non-bioabsorbable
B1015-ST	5420051303564	43764	Polymeric biliary stent, non-bioabsorbable
C0705PG	5420051304011	42701	Polymeric pancreatic stent, non-bioabsorbable
C0710PG	5420051304233	42701	Polymeric pancreatic stent, non-bioabsorbable
C0805PG	5420051304028	42701	Polymeric pancreatic stent, non-bioabsorbable
C0810PG	5420051304332	42701	Polymeric pancreatic stent, non-bioabsorbable
C1005PG	5420051303243	42701	Polymeric pancreatic stent, non-bioabsorbable
C1010PG	5420051303250	42701	Polymeric pancreatic stent, non-bioabsorbable
C1015PG	5420051306077	42701	Polymeric pancreatic stent, non-bioabsorbable
EZYFLEX0707	5420051302260	46689	Endoscopic stent-placement system
EZYFLEX0712	5420051302314	46689	Endoscopic stent-placement system
EZYFLEX0805	5420051302338	46689	Endoscopic stent-placement system
EZYFLEX0809	5420051302253	46689	Endoscopic stent-placement system
EZYFLEX0815	5420051302369	46689	Endoscopic stent-placement system
EZYFLEX1007	5420051302383	46689	Endoscopic stent-placement system
EZYFLEX1009	5420051302390	46689	Endoscopic stent-placement system
EZYFLEX1011	5420051307296	46689	Endoscopic stent-placement system
EZYFLEX1015	5420051302406	46689	Endoscopic stent-placement system
P0503-0PG	5420051303946	42701	Polymeric pancreatic stent, non-bioabsorbable
P0503-1PG	5420051303953	42701	Polymeric pancreatic stent, non-bioabsorbable
P0505-0PG	5420051303960	42701	Polymeric pancreatic stent, non-bioabsorbable
P0505-1PG	5420051303977	42701	Polymeric pancreatic stent, non-bioabsorbable
P0711-1	5420051304387	42701	Polymeric pancreatic stent, non-bioabsorbable
B0705-ST	5420051303908	43764	Polymeric biliary stent, non-bioabsorbable
B0707-ST	5420051303892	43764	Polymeric biliary stent, non-bioabsorbable
B0709-ST	5420051303885	43764	Polymeric biliary stent, non-bioabsorbable
B0712-ST	5420051303878	43764	Polymeric biliary stent, non-bioabsorbable
B0715-ST	5420051303861	43764	Polymeric biliary stent, non-bioabsorbable
B0805-ST	5420051303854	43764	Polymeric biliary stent, non-bioabsorbable
B0807-ST	5420051303847	43764	Polymeric biliary stent, non-bioabsorbable
B0809-ST	5420051303830	43764	Polymeric biliary stent, non-bioabsorbable
B0812-ST	5420051303823	43764	Polymeric biliary stent, non-bioabsorbable
B0815-ST	5420051303816	43764	Polymeric biliary stent, non-bioabsorbable
B1005-ST	5420051303809	43764	Polymeric biliary stent, non-bioabsorbable
B1007-ST	5420051303793	43764	Polymeric biliary stent, non-bioabsorbable
B1009	5420051300471	43764	Polymeric biliary stent, non-bioabsorbable
B1010	5420051307258	43764	Polymeric biliary stent, non-bioabsorbable
B1012	5420051300488	43764	Polymeric biliary stent, non-bioabsorbable
B1015	5420051300495	43764	Polymeric biliary stent, non-bioabsorbable
C0703PG	5420051304219	42701	Polymeric pancreatic stent, non-bioabsorbable
C0707PG	5420051304226	42701	Polymeric pancreatic stent, non-bioabsorbable
C0803PG	5420051304240	42701	Polymeric pancreatic stent, non-bioabsorbable
C0807PG	5420051304257	42701	Polymeric pancreatic stent, non-bioabsorbable
C1003PG	5420051304271	42701	Polymeric pancreatic stent, non-bioabsorbable
C1007PG	5420051304288	42701	Polymeric pancreatic stent, non-bioabsorbable
C1012PG	5420051306060	42701	Polymeric pancreatic stent, non-bioabsorbable
EZYFLEX0705	5420051302291	46689	Endoscopic stent-placement system
EZYFLEX0709	5420051302307	46689	Endoscopic stent-placement system
EZYFLEX0715	5420051302321	46689	Endoscopic stent-placement system
EZYFLEX0807	5420051302345	46689	Endoscopic stent-placement system
EZYFLEX0812	5420051302352	46689	Endoscopic stent-placement system
EZYFLEX1005	5420051302376	46689	Endoscopic stent-placement system
EZYFLEX1008	5420051307272	46689	Endoscopic stent-placement system
EZYFLEX1010	5420051307289	46689	Endoscopic stent-placement system
EZYFLEX1012	5420051302277	46689	Endoscopic stent-placement system
P0503	5420051303137	42701	Polymeric pancreatic stent, non-bioabsorbable
P0503-1	5420051303236	42701	Polymeric pancreatic stent, non-bioabsorbable
P0505	5420051303205	42701	Polymeric pancreatic stent, non-bioabsorbable
P0505-1	5420051303212	42701	Polymeric pancreatic stent, non-bioabsorbable
P0709-1	5420051304370	42701	Polymeric pancreatic stent, non-bioabsorbable

Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Cysto-Gastro Sets
Basic UDI-DI:	54200513-TF02-CYS-SU-GQ
Classification:	Class IIb, Rule 9
Conformity assessment route:	MDD Annex II Excluding Article 4
Models:	See attachment

G-Flex Europe SPRL declares on our own responsibility that the medical device describe above are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) as amended by Directive 2007/47/EC and of its transpositions in national laws and are in conformity with the relevant harmonized standards EN 1041:2008/A1:2013; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999; ASTM F1980-16; EN 556-1:2001; EN ISO 10993-7:2008; EN ISO 11607-1:2017; EN ISO 11607-2:2017; EN ISO 11737-2:2009; EN ISO 14644-1:2015; EN ISO 14644-2:2015; ISO 11135:2014; ISO 11138-1:2017; ISO 11138-2:2017; ISO 11737-1:2018; ASTM D7386-16; DIN 13273-7:2003; DIN EN 1618:1997; EN60601-1:2006; EN 60601-1-1-6:2010; EN 60601-2-2:2017; ISO 80369-7:2016.

This statement of conformity is only valid in connection with a signed Delivery Note for the respective Lot number of produced devices.

The device fulfill the essential requirements of Annex I of the MDD.

Notify Body:	SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp - Belgium
NB identification number:	1639
Expiry Date:	01/jun/2023
Place and date of issue:	Nivelles, 24/03/2022

Thierry CREMER - Quality Manager

G-Flex Europe SPRL - Simple & Performing
VAT: BE0876.308.490 Certified ISO 13485

Declaration of Conformity

Attachment

Product Name: Cysto-Gastro Sets

Basic UDI-DI: 54200513-TF02-CYS-SU-GQ

Reference	UDI-DI	GMDN	GMDN Term
CYSTO06U	5420051302734	65185	ERCP catheter, non-balloon, electrosurgical
CYSTO10U	5420051302758	65185	ERCP catheter, non-balloon, electrosurgical
CYSTO85U	5420051302741	65185	ERCP catheter, non-balloon, electrosurgical
CYSTO08UK	5420051306091	65185	ERCP catheter, non-balloon, electrosurgical
CYSTO10UK	5420051304165	65185	ERCP catheter, non-balloon, electrosurgical

Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Dilation Balloon
Basic UDI-DI:	54200513-TF03-DBC-SU-35
Classification:	Class IIa, Rule 5
Conformity assessment route:	MDD Annex II Excluding Article 4
Models:	See attachment

G-Flex Europe SPRL declares on our own responsibility that the medical device describe above are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) as amended by Directive 2007/47/EC and of its transpositions in national laws and are in conformity with the relevant harmonized standards EN 1041:2008/A1:2013; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999; ASTM F1980-16; EN 556-1:2001; EN ISO 10993-7:2008; EN ISO 11607-1:2017; EN ISO 11607-2:2017; EN ISO 11737-2:2009; EN ISO 14644-1:2015; EN ISO 14644-2:2015; ISO 11135:2014; ISO 11138-1:2017; ISO 11138-2:2017; ISO 11737-1:2018; ASTM D7386-16; ISO 80369-7:2016.

This statement of conformity is only valid in connection with a signed Delivery Note for the respective Lot number of produced devices.

The device fulfill the essential requirements of Annex I of the MDD.

Notify Body:	SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp - Belgium
NB identification number:	1639
Expiry Date:	01/jun/2023
Place and date of issue:	Nivelles, 24/03/2022

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Declaration of Conformity

Attachment

Product Name: Dilation Balloon

Basic UDI-DI: 54200513-TF03-DBC-SU-35

Reference	UDI-DI	GMDN	GMDN Term
EZM0430	5420051300648	45712	Gastrointestinal/biliary dilation balloon catheter
EZM0630P	5420051306626	45712	Gastrointestinal/biliary dilation balloon catheter
EZM0655	5420051302468	45712	Gastrointestinal/biliary dilation balloon catheter
EZM0830P-SW	5420051306565	45712	Gastrointestinal/biliary dilation balloon catheter
EZM1030P	5420051302888	45712	Gastrointestinal/biliary dilation balloon catheter
EZM1030P-SW	5420051306572	45712	Gastrointestinal/biliary dilation balloon catheter
EZM1055-120	5420051302963	45712	Gastrointestinal/biliary dilation balloon catheter
EZM1230P-120	5420051304400	45712	Gastrointestinal/biliary dilation balloon catheter
EZM1255	5420051301683	45712	Gastrointestinal/biliary dilation balloon catheter
EZM1555	5420051300709	45712	Gastrointestinal/biliary dilation balloon catheter
EZM1855	5420051300716	45712	Gastrointestinal/biliary dilation balloon catheter
EZM0430-SW	5420051306541	45712	Gastrointestinal/biliary dilation balloon catheter
EZM0630P-SW	5420051306558	45712	Gastrointestinal/biliary dilation balloon catheter
EZM0830P	5420051302154	45712	Gastrointestinal/biliary dilation balloon catheter
EZM0855	5420051301959	45712	Gastrointestinal/biliary dilation balloon catheter
EZM1030P-120	5420051304394	45712	Gastrointestinal/biliary dilation balloon catheter
EZM1055	5420051301690	45712	Gastrointestinal/biliary dilation balloon catheter
EZM1230P	5420051302895	45712	Gastrointestinal/biliary dilation balloon catheter
EZM1230P-SW	5420051306589	45712	Gastrointestinal/biliary dilation balloon catheter
EZM1255-120	5420051302987	45712	Gastrointestinal/biliary dilation balloon catheter
EZM1555-120	5420051302970	45712	Gastrointestinal/biliary dilation balloon catheter
EZM1855-120	5420051302994	45712	Gastrointestinal/biliary dilation balloon catheter

Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Disposable Endoscopic Forceps & Retrievers
Basic UDI-DI:	54200513-TF04-FBR-SU-A3
Classification:	Class IIa, Rule 5
Conformity assessment route:	MDD Annex II Excluding Article 4
Models:	See attachment

G-Flex Europe SPRL declares on our own responsibility that the medical device describe above are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) as amended by Directive 2007/47/EC and of its transpositions in national laws and are in conformity with the relevant harmonized standards EN 1041:2008/A1:2013; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999; ASTM F1980-16; EN 556-1:2001; EN ISO 10993-7:2008; EN ISO 11607-1:2017; EN ISO 11607-2:2017; EN ISO 11737-2:2009; EN ISO 14644-1:2015; EN ISO 14644-2:2015; ISO 11135:2014; ISO 11138-1:2017; ISO 11138-2:2017; ISO 11737-1:2018; ASTM D4169-16; EN ISO 7153-1:2016; EN10088-1:2014.

This statement of conformity is only valid in connection with a signed Delivery Note for the respective Lot number of produced devices.

The device fulfill the essential requirements of Annex I of the MDD.

Notify Body:	SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp - Belgium
NB identification number:	1639
Expiry Date:	01/jun/2023
Place and date of issue:	Nivelles, 24/03/2022

Thierry CREMER - Quality Manager

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Declaration of Conformity

Attachment

Product Name: Disposable Endoscopic Forceps & Retrievers

Basic UDI-DI: 54200513-TF04-FBR-SU-A3

Reference	UDI-DI	GMDN	GMDN Term
GF1222	5420051300839	33199	Flexible endoscopic tissue manipulation forceps, single-use
GF4500-120	5420051304134	33199	Flexible endoscopic tissue manipulation forceps, single-use
GF4502	5420051304141	33199	Flexible endoscopic tissue manipulation forceps, single-use
GF4576PG	5420051303533	33199	Flexible endoscopic tissue manipulation forceps, single-use
U822-165	5420051301973	33199	Flexible endoscopic tissue manipulation forceps, single-use
U870-180	5420051306411	33199	Flexible endoscopic tissue manipulation forceps, single-use
GF4500	5420051302710	33199	Flexible endoscopic tissue manipulation forceps, single-use
GF4501	5420051302727	33199	Flexible endoscopic tissue manipulation forceps, single-use
GF4575PG	5420051301317	33199	Flexible endoscopic tissue manipulation forceps, single-use
U622-165	5420051301966	33199	Flexible endoscopic tissue manipulation forceps, single-use
U860-230	5420051303007	33199	Flexible endoscopic tissue manipulation forceps, single-use
U870-230	5420051305841	33199	Flexible endoscopic tissue manipulation forceps, single-use

Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Multiband Ligator, for treatment of Oesophageal Varices
Basic UDI-DI:	54200513-TF05-MBL-SU-CF
Classification:	Class IIa, Rule 5
Conformity assessment route:	MDD Annex II Excluding Article 4
Models:	See attachment

G-Flex Europe SPRL declares on our own responsibility that the medical device describe above are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) as amended by Directive 2007/47/EC and of its transpositions in national laws and are in conformity with the relevant harmonized standards EN 1041:2008/A1:2013; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999; EN ISO 10993-4:2009; EN ISO 10993-11:2009; EN ISO 14644-1:2015; EN ISO 14644-2:2015; ISO 80369-7:2016.

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The device fulfill the essential requirements of Annex I of the MDD.

Notify Body:	SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp - Belgium
NB identification number:	1639
Expiry Date:	01/jun/2023
Place and date of issue:	Nivelles, 24/03/2022

Thierry CREMER - Quality Manager

G-Flex Europe SPRL - Simple & Performing
VAT: BE0876.308.490 Certified ISO 13485

Declaration of Conformity

Attachment

Product Name: Multiband Ligator, for treatment of Oesophageal Varices

Basic UDI-DI: 54200513-TF05-MBL-SU-CF

Reference	UDI-DI	GMDN	GMDN Term
GF-OVL100	5420051301416	46680	Oesophageal endoscopic ligator, single-use
GF-OVL300	5420051302642	46680	Oesophageal endoscopic ligator, single-use
GF-OVL510	5420051302635	46680	Oesophageal endoscopic ligator, single-use
GF-OVL901	5420051306763	46680	Oesophageal endoscopic ligator, single-use
GF-OVL100-RU	5420051303755	46680	Oesophageal endoscopic ligator, single-use
GF-OVL501	5420051302444	46680	Oesophageal endoscopic ligator, single-use
GF-OVL900	5420051306749	46680	Oesophageal endoscopic ligator, single-use

Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Extraction Basket & Lithotripsy System
Basic UDI-DI:	54200513-TF07-BKT-SU-EF
Classification:	Class IIa, Rule 6
Conformity assessment route:	MDD Annex II Excluding Article 4
Models:	See attachment

G-Flex Europe SPRL declares on our own responsibility that the medical device describe above are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) as amended by Directive 2007/47/EC and of its transpositions in national laws and are in conformity with the relevant harmonized standards EN 1041:2008/A1:2013; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999; ASTM F1980-16; EN 556-1:2001; EN ISO 10993-7:2008; EN ISO 11607-1:2017; EN ISO 11607-2:2017; EN ISO 11737-2:2009; EN ISO 14644-1:2015; EN ISO 14644-2:2015; ISO 11135:2014; ISO 11138-1:2017; ISO 11138-2:2017; ISO 11737-1:2018; ISO 80369-7:2016.

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The device fulfill the essential requirements of Annex I of the MDD.

Notify Body:	SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp - Belgium
NB identification number:	1639
Expiry Date:	01/jun/2023
Place and date of issue:	Nivelles, 24/03/2022

Thierry CREMER - Quality Manager

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Declaration of Conformity

Attachment

Product Name: Extraction Basket & Lithotripsy System

Basic UDI-DI: 54200513-TF07-BKT-SU-EF

Reference	UDI-DI	GMDN	GMDN Term
GF1614	5420051302581	46452	Biliary/urinary stone retrieval basket, single-use
GF1616	5420051302598	46452	Biliary/urinary stone retrieval basket, single-use

Reference	UDI-DI	GMDN	GMDN Term
GF1615	5420051300938	46452	Biliary/urinary stone retrieval basket, single-use

Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Disposable Hemoclip
Basic UDI-DI:	54200513-TF08-HMC-SU-DB
Classification:	Class IIb, Rule 8
Conformity assessment route:	MDD Annex II Excluding Article 4
Models:	See attachment

G-Flex Europe SPRL declares on our own responsibility that the medical device describe above are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) as amended by Directive 2007/47/EC and of its transpositions in national laws and are in conformity with the relevant harmonized standards EN 1041:2008/A1:2013; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999; ASTM F1980-16; EN 556-1:2001; EN ISO 10993-7:2008; EN ISO 11607-1:2017; EN ISO 11607-2:2017; EN ISO 11737-2:2009; EN ISO 14644-1:2015; EN ISO 14644-2:2015; ISO 11135:2014; ISO 11138-1:2017; ISO 11138-2:2017; ISO 11737-1:2018.

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The device fulfill the essential requirements of Annex I of the MDD.

Notify Body:	SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp - Belgium
NB identification number:	1639
Expiry Date:	01/jun/2023
Place and date of issue:	Nivelles, 24/03/2022

G-Flex Europe SPRL - Simple & Performing
VAT: BE0876.308.490 Certified ISO 13485

Thierry CREMER - Quality Manager

Declaration of Conformity

Attachment

Product Name: Disposable Hemoclip

Basic UDI-DI: 54200513-TF08-HMC-SU-DB

Reference	UDI-DI	GMDN	GMDN Term	Reference	UDI-DI	GMDN	GMDN Term
U2511-180	5420051306428	61207	Gastrointestinal endoscopic clip, short-term	**U2511-230**	5420051306442	61207	Gastrointestinal endoscopic clip, short-term
U2516-180	5420051306435	61207	Gastrointestinal endoscopic clip, short-term	**U2525-230**	5420051304356	61207	Gastrointestinal endoscopic clip, short-term

Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Disposable Polypectomy Snares
Basic UDI-DI:	54200513-TF09-SNR-SU-RF
Classification:	Class IIb, Rule 9
Conformity assessment route:	MDD Annex II Excluding Article 4
Models:	See attachment

G-Flex Europe SPRL declares on our own responsibility that the medical device describe above are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) as amended by Directive 2007/47/EC and of its transpositions in national laws and are in conformity with the relevant harmonized standards EN 1041:2008/A1:2013; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999; ASTM F1980-16; EN 556-1:2001; EN ISO 10993-7:2008; EN ISO 11607-1:2017; EN ISO 11607-2:2017; EN ISO 11737-2:2009; EN ISO 14644-1:2015; EN ISO 14644-2:2015; ISO 11135:2014; ISO 11138-1:2017; ISO 11138-2:2017; ISO 11737-1:2018; ASTM D7386-16; DIN 13273-7:2003; DIN EN 1618:1997; EN ISO 7153-1:2016; EN 60601-1:2006; EN 60601-2-2:2017; ISO 10088-1:2014; ISO 80369-7:2016.

This statement of conformity is only valid in connection with a signed Delivery Note for the respective Lot number of produced devices.

The device fulfill the essential requirements of Annex I of the MDD.

Notify Body:	SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp - Belgium
NB identification number:	1639
Expiry Date:	01/jun/2023
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Thierry CREMER - Quality Manager

G-Flex Europe SPRL - Simple & Performing
VAT: BE0876.308.490 Certified ISO 13485

Declaration of Conformity

Attachment

Product Name: Disposable Polypectomy Snares

Basic UDI-DI: 54200513-TF09-SNR-SU-RF

Reference	UDI-DI	GMDN	GMDN Term
GF4300	5420051306145	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4406	5420051306121	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4532R	5420051301270	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4575R	5420051301324	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4606	5420051306169	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4610	5420051306183	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4615	5420051306206	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4615R	5420051306213	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4625R	5420051306237	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4635R	5420051306251	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF481525CR	5420051306299	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4825R	5420051306275	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4301	5420051306152	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4410	5420051306138	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4564R	5420051301294	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4580R	5420051301980	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4606R	5420051306176	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4610R	5420051306190	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF461525CR	5420051306305	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4625	5420051306220	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4635	5420051306244	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4710R	5420051306282	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
GF4815R	5420051306268	58039	Endoscopic electrosurgical handpiece/electrode, monopolar, single-use

Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Non-Vascular Guidewires
Basic UDI-DI:	54200513-TF11-NGW-SU-GT
Classification:	Class IIa, Rule 7
Conformity assessment route:	MDD Annex II Excluding Article 4
Models:	See attachment

G-Flex Europe SPRL declares on our own responsibility that the medical device describe above are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) as amended by Directive 2007/47/EC and of its transpositions in national laws and are in conformity with the relevant harmonized standards EN 1041:2008/A1:2013; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999; ASTM F1980-16; EN 556-1:2001; EN ISO 10993-7:2008; EN ISO 11607-1:2017; EN ISO 11607-2:2017; EN ISO 11737-2:2009; EN ISO 14644-1:2015; EN ISO 14644-2:2015; ISO 11135:2014; ISO 11138-1:2017; ISO 11138-2:2017; ISO 11737-1:2018; ASTM D4169 - 16.

This statement of conformity is only valid in connection with a signed Delivery Note for the respective Lot number of produced devices.

The device fulfill the essential requirements of Annex I of the MDD.

Notify Body:	SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp - Belgium
NB identification number:	1639
Expiry Date:	01/jun/2023
Place and date of issue:	Nivelles, 24/03/2022

Thierry CREMER - Quality Manager

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Declaration of Conformity

Attachment

Product Name: Non-Vascular Guidewires

Basic UDI-DI: 54200513-TF11-NGW-SU-GT

Reference	UDI-DI	GMDN	GMDN Term
21435400BS	5420051300136	46691	Gastro-urological guidewire, single-use
GW01-35260	5420051302826	46691	Gastro-urological guidewire, single-use
GW01-35450-S	5420051304110	46691	Gastro-urological guidewire, single-use
GW09-001	5420051303984	46691	Gastro-urological guidewire, single-use
GW01-25450	5420051303519	46691	Gastro-urological guidewire, single-use
GW01-35450	5420051302505	46691	Gastro-urological guidewire, single-use
GW02-35300	5420051303731	46691	Gastro-urological guidewire, single-use

Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Sphincterotomes/Papillotomes
Basic UDI-DI:	54200513-TF12-SPH-SU-JP
Classification:	Class IIb, Rule 9
Conformity assessment route:	MDD Annex II Excluding Article 4
Models:	See attachment

G-Flex Europe SPRL declares on our own responsibility that the medical device describe above are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) as amended by Directive 2007/47/EC and of its transpositions in national laws and are in conformity with the relevant harmonized standards EN 1041:2008/A1:2013; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999; ASTM F1980-16; EN 556-1:2001; EN ISO 10993-7:2008; EN ISO 11607-1:2017; EN ISO 11607-2:2017; EN ISO 11737-2:2009; EN ISO 14644-1:2015; EN ISO 14644-2:2015; ISO 11135:2014; ISO 11138-1:2017; ISO 11138-2:2017; ISO 11737-1:2018; DIN 13273-7:2003; DIN EN 1618:1997; EN 60601-1:2005/AMD1:2012; IEC 60601-2-2:2017; EN 60601-1-6:2010; ISO 80369-7:2016.

This statement of conformity is only valid in connection with a signed Delivery Note for the respective Lot number of produced devices.

The device fulfill the essential requirements of Annex I of the MDD.

Notify Body:	SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp - Belgium
NB identification number:	1639
Expiry Date:	01/jun/2023
Place and date of issue:	Nivelles, 24/03/2022

Thierry CREMER - Quality Manager

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VAT: BE0876.308.490 Certified ISO 13485

Declaration of Conformity

Attachment

Product Name: Sphincterotomes/Papillotomes

Basic UDI-DI: 54200513-TF12-SPH-SU-JP

Reference	UDI-DI	GMDN	GMDN Term
515GW	5420051301942	65185	ERCP catheter, non-balloon, electrosurgical
520TL-M	5420051306329	65185	ERCP catheter, non-balloon, electrosurgical
520TL-SW	5420051306312	65185	ERCP catheter, non-balloon, electrosurgical
525TL-M	5420051306343	65185	ERCP catheter, non-balloon, electrosurgical
525TL-MSWR	5420051306350	65185	ERCP catheter, non-balloon, electrosurgical
530TLSC	5420051300303	65185	ERCP catheter, non-balloon, electrosurgical
GW08-000HF	5420051303380	65185	ERCP catheter, non-balloon, electrosurgical
K18NTL-SW	5420051306374	65185	ERCP catheter, non-balloon, electrosurgical
520TL	5420051302499	65185	ERCP catheter, non-balloon, electrosurgical
520TL-MSWR	5420051306336	65185	ERCP catheter, non-balloon, electrosurgical
525TL	5420051300280	65185	ERCP catheter, non-balloon, electrosurgical
525TL-MR	5420051306534	65185	ERCP catheter, non-balloon, electrosurgical
525TL-SW	5420051306367	65185	ERCP catheter, non-balloon, electrosurgical
530TLSC-MR	5420051306695	65185	ERCP catheter, non-balloon, electrosurgical
K18NTL	5420051302925	65185	ERCP catheter, non-balloon, electrosurgical
K18SP	5420051301508	65185	ERCP catheter, non-balloon, electrosurgical

Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Disposable Biopsy Forceps
Basic UDI-DI:	54200513-TF14-BBF-SU-4Q
Classification:	Class IIa, Rule 6
Conformity assessment route:	MDD Annex II Excluding Article 4
Models:	See attachment

G-Flex Europe SPRL declares on our own responsibility that the medical device describe above are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) as amended by Directive 2007/47/EC and of its transpositions in national laws and are in conformity with the relevant harmonized standards EN 1041:2008/A1:2013; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999; ASTM F1980-16; EN 556-1:2001; EN ISO 10993-7:2008; EN ISO 11607-1:2017; EN ISO 11607-2:2017; EN ISO 11737-2:2009; EN ISO 14644-1:2015; EN ISO 14644-2:2015; ISO 11135:2014; ISO 11138-1:2017; ISO 11138-2:2017; ISO 11737-1:2018; ASTM D4169-16; EN ISO 7153-1:2016; EN10088-1:2014.

This statement of conformity is only valid in connection with a signed Delivery Note for the respective Lot number of produced devices.

The device fulfill the essential requirements of Annex I of the MDD.

Notify Body:	SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp - Belgium
NB identification number:	1639
Expiry Date:	01/jun/2023
Place and date of issue:	Nivelles, 24/03/2022

Thierry CREMER - Quality Manager

G-Flex Europe SPRL - Simple & Performing
G-Flex
VAT: BE0876.308.490 Certified ISO 13485

Declaration of Conformity

Attachment

Product Name: Disposable Biopsy Forceps

Basic UDI-DI: 54200513-TF14-BBF-SU-4Q

Reference	UDI-DI	GMDN	GMDN Term
U120C	5420051302420	38711	Flexible endoscopic biopsy forceps, single-use
U160C	5420051301607	38711	Flexible endoscopic biopsy forceps, single-use
U160SC	5420051301621	38711	Flexible endoscopic biopsy forceps, single-use
U230C	5420051301638	38711	Flexible endoscopic biopsy forceps, single-use
U422-180	5420051302192	38711	Flexible endoscopic biopsy forceps, single-use
U422-230	5420051302208	38711	Flexible endoscopic biopsy forceps, single-use
U422-230S	5420051306107	38711	Flexible endoscopic biopsy forceps, single-use
U160	5420051306039	38711	Flexible endoscopic biopsy forceps, single-use
U160PC	5420051302512	38711	Flexible endoscopic biopsy forceps, single-use
U230	5420051306053	38711	Flexible endoscopic biopsy forceps, single-use
U230SC	5420051301645	38711	Flexible endoscopic biopsy forceps, single-use
U422-180S	5420051306114	38711	Flexible endoscopic biopsy forceps, single-use
U422-230LC	5420051303748	38711	Flexible endoscopic biopsy forceps, single-use

Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Extraction Basket & Lithotripsy System
Basic UDI-DI:	54200513-TF07-BKT-RU-EA
Classification:	Class I, Rule 5
Conformity assessment route:	MDD Annex VII and Article 10 of the Belgian Royal Decree of March 18th 1999 on Medical
Models:	See attachment

G-Flex Europe SPRL declares on our own responsibility that the medical device describe above are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) as amended by Directive 2007/47/EC and of its transpositions in national laws and are in conformity with the relevant harmonized standards EN 1041:2008/A1:2013; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999; ISO 17664:2017.

This statement of conformity is only valid in connection with a signed Delivery Note for the respective Lot number of produced devices.

The device fulfill the essential requirements of Annex I of the MDD.

Place and date of issue: Nivelles, 24/03/2022

G-Flex Europe SPRL - Simple & Performing
G-Flex
VAT: BE0876.308.490 Certified ISO 13485

Thierry CREMER - Quality Manager

Declaration of Conformity

Attachment

Product Name: Extraction Basket & Lithotripsy System

Basic UDI-DI: 54200513-TF07-BKT-RU-EA

Reference	UDI-DI	GMDN	GMDN Term
22640	5420051300204	46716	Biliary/urinary stone retrieval basket, reusable
GF265GW	5420051301126	46716	Biliary/urinary stone retrieval basket, reusable
GF267GW	5420051301140	46716	Biliary/urinary stone retrieval basket, reusable
GF641	5420051301409	46716	Biliary/urinary stone retrieval basket, reusable

Reference	UDI-DI	GMDN	GMDN Term
22660	5420051300211	46716	Biliary/urinary stone retrieval basket, reusable
GF266GW	5420051301133	46716	Biliary/urinary stone retrieval basket, reusable
GF527	5420051301362	46716	Biliary/urinary stone retrieval basket, reusable

Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Bite Block
Basic UDI-DI:	54200513-TF18-BBL-SU-DD
Classification:	Class I, Rule 1
Conformity assessment route:	MDD Annex VII and Article 10 of the Belgian Royal Decree of March 18th 1999 on Medical
Models:	See attachment

G-Flex Europe SPRL declares on our own responsibility that the medical device describe above are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) as amended by Directive 2007/47/EC and of its transpositions in national laws and are in conformity with the relevant harmonized standards EN 1041:2008/A1:2013; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999.

This statement of conformity is only valid in connection with a signed Delivery Note for the respective Lot number of produced devices.

The device fulfill the essential requirements of Annex I of the MDD.

Place and date of issue: Nivelles, 24/03/2022

Thierry CREMER - Quality Manager

Declaration of Conformity

Attachment

Product Name: Bite Block

Basic UDI-DI: 54200513-TF18-BBL-SU-DD

Reference	UDI-DI	GMDN	GMDN Term
U600005	5420051302475	34143	Endoscopic bite block, basic, single-use
U600006	5420051302482	34143	Endoscopic bite block, basic, single-use

Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Cleaning Brush
Basic UDI-DI:	54200513-TF19-CLB-SU-BJ
Classification:	Class I, Rule 1
Conformity assessment route:	MDD Annex VII and Article 10 of the Belgian Royal Decree of March 18th 1999 on Medical
Models:	See attachment

G-Flex Europe SPRL declares on our own responsibility that the medical device describe above are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) as amended by Directive 2007/47/EC and of its transpositions in national laws and are in conformity with the relevant harmonized standards EN 1041:2008/A1:2013; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999.

This statement of conformity is only valid in connection with a signed Delivery Note for the respective Lot number of produced devices.

The device fulfill the essential requirements of Annex I of the MDD.

Place and date of issue: Nivelles, 24/03/2022

Thierry CREMER - Quality Manager

Declaration of Conformity

Attachment

Product Name: Cleaning Brush

Basic UDI-DI: 54200513-TF19-CLB-SU-BJ

Reference	UDI-DI	GMDN	GMDN Term
GF4117BS	5420051301188	38835	Surgical instrument/endoscope cleaning brush/tool, single-use
GF4120	5420051306084	38835	Surgical instrument/endoscope cleaning brush/tool, single-use

Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Foreign Body Retrievers
Basic UDI-DI:	54200513-TF20-FBR-RU-8U
Classification:	Class I, Rule 5
Conformity assessment route:	MDD Annex VII and Article 10 of the Belgian Royal Decree of March 18th 1999 on Medical
Models:	See attachment

G-Flex Europe SPRL declares on our own responsibility that the medical device describe above are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) as amended by Directive 2007/47/EC and of its transpositions in national laws and are in conformity with the relevant harmonized standards EN 1041:2008/A1:2013; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999; ISO 17664:2017.

This statement of conformity is only valid in connection with a signed Delivery Note for the respective Lot number of produced devices.

The device fulfill the essential requirements of Annex I of the MDD.

Place and date of issue: Nivelles, 24/03/2022

Thierry CREMER - Quality Manager

Declaration of Conformity

Attachment

Product Name: Foreign Body Retrievers

Basic UDI-DI: 54200513-TF20-FBR-RU-8U

Reference	UDI-DI	GMDN	GMDN Term
18618120	5420051300051	35524	Flexible endoscopic tissue manipulation forceps, reusable
18818120	5420051300082	35524	Flexible endoscopic tissue manipulation forceps, reusable
22522160	5420051300150	35524	Flexible endoscopic tissue manipulation forceps, reusable
22622160	5420051300181	35524	Flexible endoscopic tissue manipulation forceps, reusable
22822160	5420051300228	35524	Flexible endoscopic tissue manipulation forceps, reusable
22860160	5420051306527	35524	Flexible endoscopic tissue manipulation forceps, reusable
22922230	5420051300266	35524	Flexible endoscopic tissue manipulation forceps, reusable
18618160	5420051300068	35524	Flexible endoscopic tissue manipulation forceps, reusable
18818160	5420051300099	35524	Flexible endoscopic tissue manipulation forceps, reusable
22522230	5420051300167	35524	Flexible endoscopic tissue manipulation forceps, reusable
22622230	5420051300198	35524	Flexible endoscopic tissue manipulation forceps, reusable
22822230	5420051300235	35524	Flexible endoscopic tissue manipulation forceps, reusable
22922160	5420051300259	35524	Flexible endoscopic tissue manipulation forceps, reusable

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				99 0		mtw			
DM000436621	INSTRUMENT DE BIOPSIE		Lithotomy baskets	99 03 XX XX XX	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436615	CATETER DE DILATARE		Dilatation Catheters	99 04 XX XX XX XX	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436719	INSTRUMENT CHIRURGICAL		Papillotomes	S99 02 30 51 -001	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436724	INSTRUMENT CHIRURGICAL		Polypectomy Snares	99 05XX XX XX X	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436619	AC PENTRU INJECȚIE		Injection Needles	99 09 xx xx xx xx	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436716	CUȚIT CHIRURGICAL		HF-Knives, HF-Needles	99 02 31 XX	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436816	INSTRUMENT CHIRURGICAL		Wash-Out Probes	99 01 xx xx x	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436623	INSTRUMENT DE BIOPSIE		Lithotriptors	99 03XX XX XX	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023

Страница 2 из 2 (Всего элементов: 18) 1 2

Содержит([Producatorul], 'mtw') И Содержит([Nr. catalog], '99 0')

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				99 01		mtw			
DM000436800	INSTRUMENT CHIRURGICAL		ERCP-Catheters	99 01 XX xx xx	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436811	INSTRUMENT CHIRURGICAL		Spray-Catheters	99 01 xx xx x	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436814	INSTRUMENT CHIRURGICAL		Spray-Catheters	M/ 99 01 01 31 0	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436816	INSTRUMENT CHIRURGICAL		Wash-Out Probes	99 01 xx xx x	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023

Содержит([Producatorul], 'mtw') И Содержит([Nr. catalog], '99 01')

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				00		mtw			
DM000436728	CUȚIT CHIRURGICAL		Ring Knives	04 82 10 00	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436802	INSTRUMENT CHIRURGICAL		Foreign Body Protector Hoods	10 02 00 7	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436719	INSTRUMENT CHIRURGICAL		Papillotomes	S99 02 30 51 -001	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436616	GHID PENTRU CATETER		Guide Wires	00 xx xx	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436624	CATETER DE DRENARE		Nasobiliary Drainage Catheters	04 00 XX XX XX	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023

Содержит([Producatorul], 'mtw') И Содержит([Nr. catalog], '00')

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				99 05 20		mtw			
DM000436626	INSTRUMENTE PENTRU POZIȚIONARE		Positioning Aids (Introducer, Guiding Catheters, Pushers, Extr. Snares)	99 05 20 71 21 X	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023

Содержит([Producatorul], 'mtw') И Содержит([Nr. catalog], '99 05 20')

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				04		mtw			
DM000436731	INSTRUMENT CHIRURGICAL		Stents, Pancreas	04 XX XX XX XX	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436725	CUȚIT CHIRURGICAL		Ring Knife Sets (Stents, Cyst; Ring Knives, Pusher)	0482 10 03	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436728	CUȚIT CHIRURGICAL		Ring Knives	04 82 10 00	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436710	SET DE DRENAJ ENDOSCOPIC		Cyst Drainage Sets (Stents, Cyst; Cystostomes; Pushers)	04 80 08 52 5 M	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436711	SET DE DRENAJ ENDOSCOPIC		Cyst Drainage Sets (Stents, Cyst; Cystostomes; Pushers)	04 80 10 52 5 M	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436729	INSTRUMENT CHIRURGICAL		Stents, Bile	04 XX XX XX XX	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436726	CUȚIT CHIRURGICAL		Ring Knife Sets (Stents, Cyst; Ring Knives, Pusher)	0482 10 53	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436730	INSTRUMENT CHIRURGICAL		Stents. Cyst	04 XX XX XX XX	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436615	CATETER DE DILATARE		Dilatation Catheters	99 04 XX XX XX XX	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436733	INSTRUMENT CHIRURGICAL		Stent-Sets, Pancreas (Stents, Pancreas; Guiding Catheters, Pushers)	04 XX XX XX XX	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				99 02		mtw			
DM000436712	CISTOTOM		Cystostomes	99 02 38 92	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436718	INSTRUMENT CHIRURGICAL		Papillotomes	99 02 XX XX	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436714	CUȚIT CHIRURGICAL		ESD-Knives	99 02 xx xx	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436719	INSTRUMENT CHIRURGICAL		Papillotomes	S99 02 30 51 -001	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023
DM000436716	CUȚIT CHIRURGICAL		HF-Knives, HF-Needles	99 02 31 XX	Germania	MTW-ENDOSKOPIE W. HAAG KG	ERICON S.R.L.	Rg04-000041	24-02-2023

Содержит([Producatorul], 'mtw') И Содержит([Nr. catalog], '99 02')

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
			FM-ES			finemedix			
DM000323021	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-ESN002(1800) (SOFT)A		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000323096	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-ES0004(CRESCENT) (2400)(STIFF)A		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000323091	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-ES0004(CRESCENT) (1800)(SOFT)A		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000322979	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-ESN001(1800) (SOFT)A		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000322993	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-ES0005(1600) (STIFF)A		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000323164	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-ESN006(COLD) (2400)A		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000323111	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-ES0003(CRESCENT) (1600)(STIFF)A		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000322980	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-ESN001(2200) (SOFT)A		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000323079	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-ESN002(OVAL2) (1600)A		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000323104	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-ES0002(CRESCENT) (1600)(STIFF)A		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021

Страница 1 из 26 (Всего элементов: 259) 1 2 3 4 5 6 7 ... 24 25 26

Содержит([Producatorul], 'finemedix') И Содержит([Model], 'FM-ES')

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
			FM-HG			finemedix			
DM000323184	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-HG0001(1820)		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000323185	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-HG0001(2000)		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000323183	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-HG0001(1650)		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021

Содержит([Producatorul], 'finemedix') И Содержит([Model], 'FM-HG')

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
			FM-EC			finemedix			
DM000322607	ACCESORIU PENTRU ENDOSCOPIE		FM-EC0004		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000262	29-10-2021
DM000322605	ACCESORIU PENTRU ENDOSCOPIE		FM-EC0002		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000262	29-10-2021
DM000322604	ACCESORIU PENTRU ENDOSCOPIE		FM-EC0001		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000262	29-10-2021
DM000322610	ACCESORIU PENTRU ENDOSCOPIE		FM-EC0007		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000262	29-10-2021
DM000322609	ACCESORIU PENTRU ENDOSCOPIE		FM-EC0006		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000262	29-10-2021
DM000322608	ACCESORIU PENTRU ENDOSCOPIE		FM-EC0005		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000262	29-10-2021
DM000322606	ACCESORIU PENTRU ENDOSCOPIE		FM-EC0003		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000262	29-10-2021

Содержит([Producatorul], 'finemedix') И Содержит([Model], 'FM-EC')

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Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
			FM-C			finemedix			
DM000322736	CLEMĂ ENDOSCOPICĂ	FINEMEDIX®	FM-CLD13-090(1650)		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000262	29-10-2021
DM000322718	ACCESORIU PENTRU ENDOSCOP	FINEMEDIX®	FM-CTB002N		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000262	29-10-2021
DM000322737	CLEMĂ ENDOSCOPICĂ	FINEMEDIX®	FM-CLD13-090(2300)		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000262	29-10-2021
DM000322740	CLEMĂ ENDOSCOPICĂ	FINEMEDIX®	FM-CLD16-090(1650)		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000262	29-10-2021
DM000322712	ACCESORIU PENTRU ENDOSCOP	FINEMEDIX®	FM-CTA001N		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000262	29-10-2021
DM000322711	ACCESORIU PENTRU ENDOSCOP	FINEMEDIX®	FM-CTA003		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000262	29-10-2021
DM000322709	ACCESORIU PENTRU ENDOSCOP	FINEMEDIX®	FM-CTA001		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000262	29-10-2021
DM000322728	CLEMĂ ENDOSCOPICĂ	FINEMEDIX®	FM-CLD09-090(1650)		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000262	29-10-2021
DM000322735	CLEMĂ ENDOSCOPICĂ	FINEMEDIX®	FM-CLD11-135(2300)		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000262	29-10-2021
DM000322738	CLEMĂ ENDOSCOPICĂ	FINEMEDIX®	FM-CLD13-135(1650)		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000262	29-10-2021

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Содержит([Producatorul], 'finemedix') И Содержит([Model], 'FM-C')

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
			FM-EK			finemedix			
DM000322908	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-EK0006-5-1(2300)		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000322893	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-EK0005-2(2300)A		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000322912	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-EK0006-5-3(1600)		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000322894	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-EK0005-3(1600)A		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000322888	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-EK0005-1.5(1600)A		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000322917	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-EK0006-6-1(2300)		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000322920	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-EK0006-6-2(2300)		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000322921	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-EK0006-6-3(1600)		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000322909	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-EK0006-5-2(1600)		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021
DM000322881	ACCESORIU PENTRE ENDOSCOPIE	FINEMEDIX®	FM-EK0003-3(1820)A		Japonia	FINEMEDIX CO., LTD	SOFRAGRUP S.R.L.	Rg04-000276	10-11-2021

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Содержит([Producatorul], 'finemedix') И Содержит([Model], 'FM-EK')