MED CERT®

Certification. Medical Only.

Certificate

The certification 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 management system in the area of:

Design and development, manufacture, final inspection, distribution and servicing of

- **Instruments for endoscopic use and related accessories**

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: **2020-06-23**
Expiry date: **2021-07-01**

Report No.: 1484PS23F
Procedure No.: QS – 1484
Certificate No.: 1484GB445200623

Hamburg, 2020-06-23

MEDCERT Certification Body
(Markus Bianchi)

Digitally signed by
Date: 2020.11.22 17
Reason: MoldSign S
Location: Moldova

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 is a DAkkS accredited management systems certification body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

MED CERT®

Certification. Medical Only.

Appendix of certificate

Procedure No.: QS – 1484
Certificate No.: 1484GB445200623

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.

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

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,
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10. Unterschrift / Signature

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

A4 / 07.17

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Zürich, 8th April 2020
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Fee CHF 20.00

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Bestätigt / Certified
5. In / at 8090 Zürich / Zurich
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7. durch die Staatskanzlei des Kantons Zürich
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8. unter Nr. / under N° 1179273/2020
9. Stempel/Siegel, Stamp/seal
10. Unterschrift / Signature

S. Overkott

simple and performing
www.g-flex.com

Declaration of Conformity

G-Flex Europe SPRL
20, Rue de l'Industrie
1400 - Nivelles Belgium

declares on our own responsibility that the medical device:

Product	Reference	Class	Rule
MULTIBAND LIGATOR	GF-OVL100-V2, GF-OVL200, GF-OVL200-RL, GF-OVL200-V2, GF-OVL300-V2, GF-OVL510, GF-OVL501-V2, GF-OVL100-LF, GF-OVL100-V3, GF-OVL100-LF-V2, GF-OVL300, GF-OVL501, GF-OVL100, GF-OVL510-V2, GF-OVL100-LC-01, GF-OVL100-R, GF-OVL100-RU	I	5

are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) and of its transpositions in national laws.
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.
The conformity assessment procedure was established in accordance with:

Notify Body	**SGS United Kingdom Limited** Unit 202B, Worle Parkway, Weston-super-Mare, Somerset, BS22 6WA - United Kingdom
Identificaton Number	0120
Procedure	Article 10 of the Belgian Royal Decree of March 18th 1999 on Medical Devices

The device are manufactured in the European Union.

Nivelles, 12/12/2014

Thierry CREMER
Quality Manager

G-Flex Europe Sprl - Simple & Performing
ISO 9001
www.g-flex.com
ISO 13485
VAT: BE0876.308.490

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: Fortune Medical Instrument Corp.
6F., No. 29, Sec. 2
Jhongjheng E. Rd.
Danshuei Dist.
New Taipei City
251
Taiwan

Holds Certificate No: **MD 588797**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture and sales of sterile urological catheters and accessories, catheter spigot, drainage tube and accessories, endotracheal tube, tracheostomy tube, reservoir, epistaxis device, gastrointestinal tube and implantable vascular access port and accessories, silicone surgical ruler and silicone vessel ID loops, and of non-sterile laryngeal mask tube, resuscitator and accessories, vacuum suction and accessories, tracheal tube fixation device.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk – Medical Devices

Originally Registration Date: 2012-08-23
Effective Date: 2016-08-09
Latest Revision Date: 2017-11-24
Expiry Date: 2019-08-08

UKAS QUALITY MANAGEMENT 003

...making excellence a habit.™

Certificate No: **MD 588797**

Location	Registered Activities
Fortune Medical Instrument Corp. 6F., No. 29, Sec. 2 Jhongjheng E. Rd. Danshuei Dist. New Taipei City 251 Taiwan	The sales of sterile urological catheters and accessories, catheter spigot, drainage tube and accessories, endotracheal tube, tracheostomy tube, reservoir, epistaxis device, gastrointestinal tube and implantable vascular access port and accessories, silicone surgical ruler and silicone vessel ID loops, and of non-sterile laryngeal mask tube, resuscitator and accessories, vacuum suction and accessories, tracheal tube fixation device.
Fortune Medical Instrument Corp. No. 256, Changchun 2nd Rd. Jhongli Dist. Taoyuan City 320 Taiwan	The design, development and manufacture of sterile urological catheters and accessories, catheter spigot, drainage tube and accessories, endotracheal tube, tracheostomy tube, reservoir, epistaxis device, gastrointestinal tube and implantable vascular access port and accessories, silicone surgical ruler and silicone vessel ID loops, and of non-sterile laryngeal mask tube, resuscitator and accessories, vacuum suction and accessories, tracheal tube fixation device.

Originally Registration Date: 2012-08-23 Effective Date: 2016-08-09

Latest Revision Date: 2017-11-24 Expiry Date: 2019-08-08

Certificate BE13/223575066

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

ISO 13485:2003
EN ISO 13485:2012

For the following activities

Design and development, manufacture and distribution of sterile and non-sterile instruments and accessories for applications in endoscopy, urology and respiratory.

This certificate is valid from 3 September 2015 until 1 June 2018 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 1 May 2018.
Issue 5. Certified since 1 April 2013.

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 13485-2 1114

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 588902**

Issued To: **Fortune Medical Instrument Corp**
6F., No. 29, Sec. 2, Jhongjheng E.Rd.,
Danshuei Dist,
New Taipei City
251
Taiwan

In respect of:

The design, manufacture and final inspection of sterile urological catheters and accessories, drainage tube and accessories, endotracheal tube, tracheostomy tube, reservoir, gastrointestinal tube and accessories, silicone surgical ruler and silicone vessel ID loops and non-sterile laryngeal mask tube.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2012-08-27** Date: **2019-02-25** Expiry Date: **2023-09-24**

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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 588902**
Date:	**2019-02-25**
Issued To:	**Fortune Medical Instrument Corp** **6F., No. 29, Sec. 2, Jhongjheng E.Rd.,** **Danshuei Dist,** **New Taipei City** **251** **Taiwan**

Subcontractor:	**Service(s) supplied**
Fortune Medical Instrument Corp No. 256, Changchun 2nd Road Jhongli Dist Taoyuan City 320 Taiwan	**Design** **ETO Sterilization** **Final Inspection** **Manufacture** **Regulatory Compliance**
PRIM S.A. C/F 15, Pol. Ind. No.1 28938 Mostoles Madrid Spain	**EU Representative**

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By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 588902**

Date: **2019-02-25**

Issued To: **Fortune Medical Instrument Corp**
6F., No. 29, Sec. 2, Jhongjheng E.Rd.,
Danshuei Dist,
New Taipei City
251
Taiwan

Date	Reference Number	Action
27 August 2012	7859139	First issue. Transfer from another Notified Body, TÜV SÜD, certificate reference G1 11 06 65095 006.
01 October 2013	8063652	Certificate renewal.
05 October 2018	9642053	Amendment to scope to add in "and accessories" for sterile urological catheters, "and accessories" for sterile drainage tube, addition of sterile Silicone surgical ruler, sterile Silicone vessel ID loops. Administrative changes to the address for the head office and the subcontractor, Fortune Medical Instrument Corp, No 256, Changchun 2nd Road. Removal of vacuum suction and resuscitator. Certificate renewal.
Current	7932553	Traceable to NB 0086.

Certificate

SERTİFİKA

TÜRCERT Sertifikasyon Merkezi
iş bu belge ile/TÜRCERT Certification Body
with this document.

TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SAN. VE TIC. A.Ş.

YAKUPLU MAH. BİRLİK CAD. NO:32/1 BEYLİKDÜZÜ İSTANBUL TÜRKİYE

şirketinin;/ of the company

RÖNTGEN SOLÜSYONLARI, TIBBİ CİHAZ DEZENFEKTANLARI VE MEDİKAL CİHAZLAR İÇİN STERİL BUĞU ÖNLEYİCİ SOLÜSYON, STERİL VE STERİL OLMAYAN KAYGANLAŞTIRICI JELLER, DOĞUM JELLERİ, STERİL VE STERİL OLMAYAN ULTRASON JELLERİ, STERİL VE STERİL OLMAYAN BURUN SOLÜSYONLARI, BİT ŞAMPUANI VE SPREYİ VE SMEAR DOKU SABİTLEYİCİ SPREYİNİN TASARIMI, ÜRETİMİ VE SATIŞI

MANUFACTURING AND SALES OF MEDICAL X-RAY SOLUTIONS, MEDICAL DEVICE DISINFECTANT, STERILE ANTIFOG SOLUTION FOR MEDICAL DEVICES, STERILE AND NON-STERILE LUBRICANT GELS, OBSTETRIC GEL, STERILE & NON-STERILE ULTRASOUND GELS, STERILE & NON-STERILE NASAL SOLUTIONS, ANTI-LICE AND NITS SHAMPOO AND SPRAY AND SMEAR SPRAY

belirlenen standardın uygulanması konusunda tıbbi cihazlar için yönetim sistemi yürürlüğe koyduğunu ve uygulamakta olduğunu taahhüt eder./ Effective medical devices management system and guarenteesthat you put in to apply

2018101013284-01MDMS Sayılı rapordaki inceleme ile/
2018101013284-01MDMSwith the nr. examination report;

TS EN ISO 13485:2016

şartlarının sağlanmış olduğu kanıtlanmıştır, iş bu sertifika yıllık ara denetimlerinin yapılması kaydıyla **08.08.2021** tarihine kadar geçerlidir./ Its proven that requirements are provided. This certificate is valid until **08.08.2021** with the condition of surveillance audits done

Sertifika Kayıt No/ Certificate Registration Nr : 2018101013284-01
Sertifika Yayın Tarihi / Date of Issue : 10.10.2018
Sertifika Geçerlilik Tarihi / Certificate Validity Date : 08.08.2021

TÜRCERT

Türcert A.Ş.
Belgelendirme Bölümü Adına

ÖSAS
ÖSTERREICH
Spezielle Akkreditierung Service
austria
ÖSAS Ö-41

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME ANONİM ŞİRKETİ
Adres : Sanayi Mh. Atatürk Cd. No 57/17 Güngören / İstanbul - Türkiye
Telefon: 0 212 909 35 90 - 0 312 500 00 10 www.turcert.com