3EC International

3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC CERTIFICATE

No. 2013-MDD/QS-032

issued in compliance with the Council Directive 93/42/EEC as amended by 2007/47/EC, which is implemented by the Slovak Government Decree No. 582/2008 Coll. certifies that the medical device of Class IIa & IIb,

Medical Devices for Gastroenterology
(for detailed list refer to Annex, pages 1 to 3)

manufactured by company

Marflow AG
Soodstrasse 57, CH-8134 Adliswil, Zürich, Switzerland

is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended by 2007/47/EC.

The Notified Body No. 2265 has performed an audit of the above device quality system. The full quality assurance system has been assessed and found that it meets the requirements above. The quality system is subject to continuous surveillance according to Annex II, Sections 3.3, and 5, of the Directive 93/42/EEC as amended 2007/47/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Reports No. 310121A and 310121B, and the Final protocol No. 310121b/2013 that is enclosed to this certificate.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced model of medical device and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until August 26th, 2019 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfilment of relevant legal and other requirements by manufacturer.

Notified body
3EC International
NB 2265
NOTIFIKOVANÁ OSOBA

In Bratislava, on August 27th, 2013

Dr. Katarína Srdošová
Responsible to act on behalf of NB 2265

Digitally signed by Bunic Gheorghe
Date: 2019.02.06 21:56:33 EET
Reason: MoldSign Signature
Location: Moldova

MED CERT®

Professional. Flexible. Medical Only.

EC-Certificate of Conformity

The Notified Body

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

herewith confirms that the company

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

has introduced, applies and maintains a Quality Assurance System
for the products / product categories:

Medical devices as per attachment

The compliance of the Quality Assurance System with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II excluding section 4

This certificate is valid until: 01 July 2020

Report No.: 1484FS18F
Process No.: QS – 1484
Certificate No.: 1484GB410150901

Hamburg, 01 September 2015

MEDCERT Certification Body
(Dr. Andreas Schich)

MEDCERT Identification No.: 0482

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

ZLG-BS-237.10.15

Lloyd's Register LRQA

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

Cook Incorporated
750 Daniels Way
Bloomington, Indiana 47404, USA

has been assessed against the requirements of Annex II of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations. In addition for Class III products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

This certificate forms part of the approval identified by certificate number UQA 4000228

Certificate No:	4000228/A
Original Approval:	April 12, 2006
Current Certificate:	January 18, 2017
Certificate Expiry:	April 30, 2019

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

Lloyd's Register
LRQA

CERTIFICATE OF APPROVAL

This is to certify that the Management System of:

Cook Incorporated
750 Daniels Way
Bloomington, Indiana 47404, USA

has been approved by Lloyd's Register Quality Assurance
to the following Quality Management System Standards:

ISO 13485:2003

The Management System is applicable to:

Design and Manufacturing of Reusable and Disposable Diagnostic and Interventional Medical Devices (including all product families listed on the attached certificate schedule), Provision of Contract Ethylene Oxide Sterilization Services and Associated Laboratory Services. Installation and Servicing of Durable Medical Equipment.

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

This certificate forms part of the approval identified by certificate number UQA 4000228

Approval
Certificate No: UQA 4000228/D

Original Approval: May 2, 2006
Effective Date: May 1, 2017
Certificate Expiry: March 1, 2019

Issued by: Lloyd's Register Quality Assurance, Inc. for and on behalf of Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
001

LRQA, Inc. 1330 Enclave Parkway, Suite 200, Houston, Texas 77077, USA
For and on behalf of LRQA Ltd. 1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom

EC Certificate Full Quality Assurance System: BE13/223575069

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

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 9 March 2016 until 1 June 2020 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 1 May 2018.
Issue 7. Certified since 1 April 2013.

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

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
SGS United Kingdom Ltd Systems & Services Certification
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

EC Certificate Production Quality Assurance System: Certificate
BE13/223575068

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 V
Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.

For the following products

Sterile Biliary Dilation Catheters
Sterile Disposable E.R.C.P. Catheters
Sterile Disposable Extraction Baskets
Sterile Endoscopic Needle
Sterile Guide Wires
Sterile Guiding Catheters, Pushers, Stent Application Systems
Sterile Mechanical Lithotriptors
Sterile Ureteral Access Sheath

This certificate is valid from 3 September 2015 until 1 June 2020 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 1 May 2018.
Issue 3. Certified since 1 April 2013.

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

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 18 0811

EC Certificate Production Quality Assurance System: Certificate
BE13/223575067

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 V

For the following products

Sterile Cold Snares

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

This certificate is valid from 3 September 2015 until 1 June 2020 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 1 May 2018.
Issue 3. Certified since 1 April 2013.

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

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 14 0215

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

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 9 March 2016 until 1 June 2020 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 1 May 2018.
Issue 7. Certified since 1 April 2013.

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

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
SGS United Kingdom Ltd Systems & Services Certification
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

MED CERT®

Professional. Flexible. Medical Only.

Certificate

The Certification Body

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

herewith confirms that the company

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

and their facilities
Sebastianusstr. 33, 35 and 52
46487 Wesel
Germany

has introduced, applies and maintains a Quality Management System in the area of:

Design, manufacture, final inspection, distribution and repair of instruments for endoscopic use and related accessories

The compliance of the Quality Management System with the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2012 + AC:2012

This certificate is valid until: 01 July 2020

Report No.: 1484FS18F
Process No.: QS – 1484
Certificate No.: 1484GB438150901

Hamburg, 01 September 2015

MEDCERT Certification Body
(Dr. Andreas Schich)

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

TRANSGLOBAL QUALITY ASSESSORS LLP

Management System Certificate

Certificate No. MD.QMS.91.006.06.16

This is certify that

Marflow AG

at

Soodstrasse 57, CH-8134 Adliswil, Zürich, Switzerland.

has been found to conform to Management System Standard

ISO 13485: 2003

This certificate valid for the following product / service ranges:

DESIGN AND MANUFACTURE OF NON-ACTIVE AND ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES FOR UROLOGY AND GASTROENTEROLOGY

Internal Certification : 23.06.2016
Valid until : 22.06.2019

(Authorized Signatory)
Transglobal Quality Assessors LLP

This is an accredited certificate authorised for issue by Accreditation Services for certifying bodies (Europe) Limited, who have assessed Transglobal Quality Assessors LLP Located at PUNE, INDIA, against defined criteria and in cognisance of ISO 17021, "Conformity Assessment Requirements for bodies providing audit and certification of management systems". This certificate is only valid when confirmed by register listed in the International register of Quality Assessed Organisation : www.irqao.com

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

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 18 01 81989 007

Manufacturer:

Changzhou Waston Medical Appliance Co., Ltd.
No.9 Xihu Road
Wujin Hi-Tech Industry Zone
213164 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

General Spinal System, Metallic Bone Plates, Metallic Bone Screws, Metallic Intramedullary Nails, Circular Staplers, Linear Staplers, PPH Staplers, Linear Cutters, Curved Cutters, Orthopaedic External Fixation System, Endoscopic Cutters

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.: SH18687EXT01

Valid from: 2018-03-08
Valid until: 2023-03-07

0405276784718

Date, 2018-01-15

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

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

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 18 01 81989 007

Facility(ies):

Changzhou Waston Medical Appliance Co., Ltd.
No.9 Xihu Road, Wujin Hi-Tech Industry Zone,
213164 Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 16 01 81989 006

Holder of Certificate: **Changzhou Waston Medical Appliance Co., Ltd.**

No.9 Xihu Road
Wujin Hi-Tech Industry Zone
213164 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Changzhou Waston Medical Appliance Co., Ltd.
No.9 Xihu Road, Wujin Hi-Tech Industry Zone,
213164 Changzhou, Jiangsu, PEOPLE'S
REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485

Scope of Certificate:

**Design and Development,
Production and Distribution of
General Spinal System, Metallic Bone Plates,
Metallic Bone Screws, Curved Cutters,
Metallic Intramedullary Nails,
Circular Staplers, Linear Staplers,
PPH Staplers, Linear Cutters,
Orthopaedic External FIxation System,
Endoscopic Cutters**

Applied Standard(s):

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

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.: SH1568704

Valid from: 2016-03-08
Valid until: 2019-03-07

Date, 2016-02-24

Stefan Preiß

04052768956231

Page 1 of 1

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

Certificate

kiwa
Partner for progress

Reg. Number	10480 - M		
Issuing date	2010-07-20	Last modification date	2016-06-24
Following renewal date	2019-02-28		

Quality Management System Certificate

ISO 13485:2003

We certify that the Quality Management System of the Organization:

X-MED S.r.l.

Is in compliance with the standard UNI CEI EN ISO 13485:2012 for the following products/services:

Design and manufacturing management of sterile protective sheats for rigid and flexible endoscopes, implantable mesh and sterile surgical kit for gynecology and critical care

Chief Operating Officer
Giampiero Belcredi

Maintenance of the certification is subject to annual survey and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

This certificate consists of 1 page.

X-MED S.r.l.
VIA STATALE SUD, 113
41037 Mirandola MO Italia

- *VIA STATALE SUD, 113 41037 Mirandola (MO) Italia (Sede Legale)*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET

IAF INTERNATIONAL ACCREDITATION FORUM

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 007A SSI N° 006G
SGA N° 010D FSM N° 004I
PRD N° 069B