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

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

Thierry CREMER
Quality Manager

Digitally signed by Bunic Gheorghe
Date: 2019.04.07 23:13:03 EEST
Reason: MoldSign Signature
Location: Moldova

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

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

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