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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 101573 0006 Rev. 00

Manufacturer:

WELLEX Company Limited
Cairo-Ismailia desert Road
Ismailia Public free Zone
41639 Ismailia City
EGYPT

Product Category(ies):

Dialysis Catheters, Guiding Catheters, Introducer Sheath Sets, Hemostatis Valves, Nephorstomy Catheters, IV Cannula with port, Guidewires for Urological Use, Diagnostic Catheters, IV Catheters for Angiography.
Retrieval Endo-bags, Veress Needles, Anaesthesia Needles, Nelaton Catheters, Foley Catheters.

Introducer Needles, AV Fistula Needles for hemodialysis, Arterial Venous Blood Line Sets for hemodialysis, 3-Way Stopcocks, and Connecting Tubes.

Biopsy Needles, Disposable Laparoscopic Trocars, Skin Staplers, Surgical Staplers Family (include: Endoscopic Linear Cutter Staplers, Linear Cutter Staplers and Stapler Cartridges, Linear Staplers, Circular Staplers, Curved Cutter Staplers and Cartridges, Prolapse Hemorrhoids Staplers), Disposable Laparoscopic Instruments (Scissors and Forceps), Reposable Laparoscopic Instruments (Scissors and Forceps) (Disposable Shaft+Reusable Handle)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G2 101573 0006 Rev. 00

Report No.: IND20190114

Valid from: 2020-09-21
Valid until: 2024-04-13

Digitally signed by Ostapciuc Alexandr
Date: 2023.08.22 14:54:20 EEST
Reason: MoldSign Signature
Location: Moldova

Date, 2020-09-21

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