



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

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-Ismaïlia desert Road
Ismaïlia Public free Zone
41639 Ismaïlia City
EGYPT

Product Category(ies):

Dialysis Catheters, Guiding Catheters, Introducer Sheath Sets,
Hemostatic Valves, Nephrostomy 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), Repposable 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

Date, 2020-09-21

Christoph Dicks
Head of Certification/Notified Body

Page 1 of 1

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