



Health Technology Certification

EC-CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM

This is to certify that the quality management system of

WELLEX Company Limited

Cairo-Ismailia Desert Road, Ismailia Public Free Zone,
41639 Ismailia City, Egypt

for design and manufacture of

- Ureteral Stents and Sets
- Ureteric Catheters
- Endotracheal Tubes
- Insulin Pen Needles
- Dormia Baskets
- Balloon Dilatation Catheters
- Ureteral Access Sheath and Dilator Sets
- Central Venous Catheters Kits

fulfills the requirements of Annex II excluding (4) of Council Directive 93/42/EEC.

The use of CE Marking followed by the HTCert Notified Body identification number 2803 for the devices listed on the certificate is hereby authorised. The certificate remains valid subject to satisfactory surveillance audits, periodic or unexpected. Any significant changes in design or manufacture may render this certificate invalid. For class III devices covered by this certificate an EC Design Examination Certificate according to Annex II, Section 4 is required. For class I sterile devices the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.

Certificate No: 1183C04210501
Issue Date: 24/05/2021
Original Approval: 24/05/2021
Valid until: 26/05/2024
References: W001 1183 01

HTCert is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification number 2803

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director

FILIPPOS KOTTIS
Certification Director