EC Certificate Full Quality Assurance System: Certificate CN14/10426

The management system of

Dalian Create Medical Products Co., Ltd.

No. IIB-31, Dalian Exp., Processing Zone, 116600, Dalian,
Liaoning Province, PEOPLE'S REPUBLIC OF CHINA

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

Sterile single use anesthesia and respiratory tube, Sterile single use gastroenterological tube, Sterile single use surgical tube, Sterile single use gastrointestinal loop fixture, Sterile single use urological catheter, Sterile single use nephrostomy catheter kit, Sterile single use PTCD Kit, Sterile single use gastrostomy kit, Sterile single use non vascular guidewire, Sterile single use endoscopic hood, Sterile implantable port for injection, Sterile single use dilator used with gastroenterological tube Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintain sterile conditions: Sterile stabilizer for catheter

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 28 July 2016 until 27 July 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 19 June 2019
Issue 5. Certified since 29 October 2014

Certification is based on reports numbered CN/DLC 7678

Authorised by

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