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, P.R. 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 All Silicone Ileus Tube;
Sterile All Silicone Penrose Drain Tube / All Silicone Multitubular Drain Tube;
Sterile Transanal Ileus Tube Set; Sterile All Silicone Endotracheal Tube
Sterile Loop Fixture Used for fixing gastric wall and abdominal wall before fistulation.
Sterile All Silicone Duodenography Balloon Tube; Sterile non vascular guidewire
Sterile All Silicone Balloon Sonde; Sterile E-V Tube (S-B Tube);
Sterile All Silicone Stomach Tube; Sterile PTC Drainage Tube;
All Silicone Gastrostomy Balloon Catheter; Sterile All Silicone Tracheostomy Tube;
Sterile All Silicone Foley Balloon Catheter; Nephrostomy Kit;
All Silicone Nephrostomy Balloon Catheter; All Silicone Malecot Catheter;
PTCD Kit; Sterile Gastrostomy Kit; All Silicone Stabilizer

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 09 August 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 19 June 2022
Issue 8. Certified since 29 October 2014

Certification is based on reports numbered CN/DLC 7678

Authorised by

Jonathan M. Hall

SGS United Kingdom Ltd, Notified Body 0120
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 0215