EC Certificate Full Quality Assurance System: Certificate CN19/41058

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

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 06 April 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 29 October 2014
and first certified by SGS Belgium NV since 16 December 2019.

Certification is based on reports numbered CN/DLC 7678

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Dalian Create Medical Products Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 2

Detailed scope

**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 non vascular guidewire
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.