

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 CNDLC 7678

Authorised by

SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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Certificate CN19/41058 continued

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.

Dalian Create Medical Products Co., Ltd.

No. IIB-31, Dalian Exp., Processing Zone,
116600, Dalian, Liaoning Province, P.R. China

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**

This corrigendum is only valid together with accompanying 93/42/EEC certificate
CN19/41058 Issue 2

Authorised by



Global Medical Devices Certification Manager

SGS Belgium NV, Notified Body 1639

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LPMD5105 – Corrigendum to Certificate

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SGS Belgium NV

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Correction Date	Correction
Change approved by SGS on 03 November 2021	To remove below devices from scope: 1. Sterile All Silicone Penrose Drain Tube / All Silicone Multitubular DrainTube 2. Sterile All Silicone Endotracheal Tube 3. Sterile All Silicone Stomach Tube 4. Sterile PTC Drainage Tube 5. Nephrostomy Kit
Change approved by SGS on 13 June 2022	1. Company name changed to "DALIAN CREATE MEDICAL PRODUCTS CO., LTD."; 2. Company address changed to "No.IIB-31, Dalian Export Processing Zone, 116600 Dalian, Liaoning Province, People's Republic of China"
Change approved by SGS on 10 August 2023	Remove one device from scope: Sterile Transanal Ileus Tube Set

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