EC Certificate Full Quality Assurance System: Certificate JP19/040486

The management system of

# Create Medic Co., Ltd.

Head Office 2-5-25 Chigasakiminami, Tsuzuki-ku, Yokohama, Kanagawa, 224-0037 Japan

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 11 September 2020 until 23 October 2023
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 29 July 2016
and first certified by SGS Belgium NV since 09 July 2019

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered JP/YOK 9151

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

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

# Create Medic Co., Ltd.

## Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 3

Detailed scope

**Sterile single-use All Silicone Urological Balloon Catheter**

**Sterile single-use All Silicone Sengstaken Blakemore Tube**

**Sterile single-use All Silicone Gastrostomy Balloon Catheter**

**Sterile single-use vascular 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.

Additional facilities

| | |
|---|---|
| **R&D Center** | **3-25-6 Tonomachi, Kawasaki-ku, Kawasaki, Kanagawa, 210-0821 Japan** |

Critical Subcontractor:

| | |
|---|---|
| **Dalian Create Medical Products Co., Ltd.** | **No. II B-31, Dalian Exp., Processing Zone, 116600 Dalian, PEOPLE'S REPUBLIC OF CHINA** |

Corrigendum to Certificate JP19/040486

# CREATE MEDIC CO., LTD.

Head Office 2-5-25 Chigasakiminami, Tsuzuki-ku, Yokohama, Kanagawa, 224-0037 Japan

**Scope:**

Sterile single-use All Silicone Urological Balloon Catheter

Sterile single-use All Silicone Sengstaken Blakemore Tube

Sterile single-use All Silicone Gastrostomy Balloon Catheter

Sterile single-use vascular catheter

This corrigendum is only valid together with accompanying 93/42/EEC certificate issue 3

| Correction Date | Correction |
|---|---|
| 18th August, 2022 | 1.Cancelled the certificate for the Class III ECDE device Sterile single-use vascular catheter , so under the influence of this cancelled device will be removed from MDD's certificate scope as well.<br><br>2. Changed company name from mixed lowercase to all uppercase<br><br>3. The company name of the sub-site, Dalian Create Medical Products Co., Ltd. is also changed from mixed lowercase to all uppercase, DALIAN CREATE MEDICAL PRODUCTS CO., LTD.<br><br>4. change the address notation of DALIAN CREATE MEDICAL PRODUCTS CO., LTD. To No. II B-31, Dalian Export Processing Zone, 116600 Dalian, Liaoning Province, People's Republic of China |

Authorised by

Global Medical Devices Certification Manager

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium

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LPMD5105 – Corrigendum to Certificate