



Certificate JP19/040485

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

ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate

This certificate is valid from 09/07/2019 until 21/12/2021
and remains valid subject to satisfactory surveillance audits.

Issue 1. Organisation certified since 01/04/2010
and first certified by SGS Belgium on 09/07/2019

Re certification audit due before 14/09/2021

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by

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Certification Manager

SGS Belgium NV

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Accreditation Number

005-QMS
EN ISO/IEC 17021-1:2015

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Create Medic Co., Ltd.

ISO 13485:2016
EN ISO 13485:2016



Issue 1

Detailed scope

Design and Development, Manufacture and Distribution of sterile single use Port System for intravenous and intra-arterial injection, 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 Endoscopic Hood, sterile Stabilizer for catheter, sterile and non-sterile Guide Wires, sterile and non-sterile Syringes, sterile and non-sterile Needles, sterile and non-sterile Dilators, sterile and non-sterile Sheaths, sterile and non-sterile Stopcocks, sterile and non-sterile single use Connectors, non-sterile Self-Catheterization Sets, sterile and non-sterile single use Tubes, Catheters, Kits and Sets

Additional facilities

R&D Center

**3-25-6 Tonomachi, Kawasaki-ku, Kawasaki,
Kanagawa, 210-0821 Japan**

Hokkaido Plant

**12-49 Okayama-cho, Iwamizawa,
Hokkaido, 079-0181 Japan**

**Mito Distribution
Center**

**234-25 Aza Akaho, Hirasu-cho, Mito, Ibaraki,
310-0853 Japan**

**Kyushu Distribution
Center**

**2-52 Makiyamakaigan, Tobata-ku, Kitakyusyu,
Fukuoka, 804-0077 Japan**



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