Certificate JP21/819943454

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 08 June 2021 until 21 December 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 14 September 2021
Issue 1. Certified since 01 April 2010

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

Authorised by

UKAS MANAGEMENT SYSTEMS
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SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

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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