



Product Service

# Certificate

No. Q5 031695 0041 Rev. 00

**Holder of Certificate:** **CREATE MEDIC CO., LTD.**  
 2-5-25 Chigasakiminami, Tsuzuki-ku  
 Yokohama, Kanagawa  
 224-0037 JAPAN

**Certification Mark:**



**Scope of Certificate:**

Design and Development, Production and Distribution of sterile Anesthesia and Respiratory Tube, sterile Assisted Reproduction Catheter, sterile Bladder Catheter and Kit, sterile Carotid Artery Shunt, sterile Cranial Drainage Tube, sterile Digestive Endoscopy Hood and Tube, sterile Dilator, sterile Electric Scalpel Cleaner, sterile Embolectomy Catheter, sterile External Drainage Catheter, Kit and Accessory, sterile Gastrointestinal Tube and Kit, sterile Gastrointestinal Feeding Tube, Kit and Accessory, sterile and non-sterile Hysterectomy Assisting Device, sterile Hysterosalpingography Catheter, sterile Infusion Device, Intermittent Self Catheter and Set, sterile Loop Fixture, sterile Nasal Wash Catheter, sterile Nephrostomy Catheter and Kit, sterile Non Vascular Guidewire, sterile Oesophageal Dilation Catheter, sterile Over Tube, sterile Puncture Needle, sterile and non-sterile Rectography Tube and Accessory, sterile Renal Cooling Catheter, sterile Respiratory Suction Tube, sterile Sengstaken Blakemore Tube, sterile Spinal Catheter, sterile Stabilizer for Catheter, sterile Stopcock, sterile Surgical Drainage Tube, sterile Syringe, sterile Ureteral Stent and Catheter, sterile Urethral Pressure Profile Catheter, sterile Urological Catheter, Kit and Accessory, sterile Uterine Dilation Catheter and Device, sterile and non-sterile Vascular Catheter, Kit and Accessory

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5\\_031695\\_0041\\_Rev.00](http://www.tuvsud.com/ps-cert?q=cert:Q5_031695_0041_Rev.00)

**Report No.:** JN2066742

**Valid from:** 2023-08-02  
**Valid until:** 2024-12-21

**Date,** 2023-08-02

Christoph Dicks  
 Head of Certification/Notified Body

# Certificate

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**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** **CREATE MEDIC CO., LTD.**  
2-5-25 Chigasakiminami, Tsuzuki-ku, Yokohama, Kanagawa,  
224-0037 JAPAN

Design and Development, Production and Distribution of sterile Anesthesia and Respiratory Tube, sterile Assisted Reproduction Catheter, sterile Bladder Catheter and Kit, sterile Carotid Artery Shunt, sterile Cranial Drainage Tube, sterile Digestive Endoscopy Hood and Tube, sterile Dilator, sterile Electric Scalpel Cleaner, sterile Embolectomy Catheter, sterile External Drainage Catheter, Kit and Accessory, sterile Gastrointestinal Tube and Kit, sterile Gastrointestinal Feeding Tube, Kit and Accessory, sterile and non-sterile Hysterectomy Assisting Device, sterile Hysterosalpingography Catheter, sterile Infusion Device, Intermittent Self Catheter and Set, sterile Loop Fixture, sterile Nasal Wash Catheter, sterile Nephrostomy Catheter and Kit, sterile Non Vascular Guidewire, sterile Oesophageal Dilation Catheter, sterile Over Tube, sterile Puncture Needle, sterile and non-sterile Rectography Tube and Accessory, sterile Renal Cooling Catheter, sterile Respiratory Suction Tube, sterile Sengstaken Blakemore Tube, sterile Spinal Catheter, sterile Stabilizer for Catheter, sterile Stopcock, sterile Surgical Drainage Tube, sterile Syringe, sterile Ureteral Stent and Catheter, sterile Urethral Pressure Profile Catheter, sterile Urological Catheter, Kit and Accessory, sterile Uterine Dilation Catheter and Device, sterile and non-sterile Vascular Catheter, Kit and Accessory

**CREATE MEDIC CO., LTD. R&D Center**  
3-25-6 Tonomachi, Kawasaki-ku, Kawasaki, Kanagawa,  
210-0821 JAPAN

Design and Development of sterile Anesthesia and Respiratory Tube, sterile Assisted Reproduction Catheter, sterile Bladder Catheter and Kit, sterile Carotid Artery Shunt, sterile Cranial Drainage Tube, sterile Digestive Endoscopy Hood and Tube, sterile Dilator, sterile Electric Scalpel Cleaner, sterile Embolectomy Catheter, sterile External Drainage Catheter, Kit and Accessory, sterile Gastrointestinal Tube and Kit, sterile Gastrointestinal Feeding Tube, Kit and Accessory, sterile and non-sterile Hysterectomy Assisting Device, sterile Hysterosalpingography Catheter, sterile Infusion Device, Intermittent Self Catheter and Set, sterile Loop Fixture, sterile Nasal Wash Catheter, sterile Nephrostomy Catheter and Kit, sterile Non Vascular Guidewire, sterile Oesophageal Dilation Catheter, sterile Over Tube, sterile Puncture Needle, sterile and non-sterile Rectography Tube and Accessory, sterile Renal Cooling Catheter, sterile Respiratory Suction Tube, sterile

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Sengstaken Blakemore Tube, sterile Spinal Catheter, sterile Stabilizer for Catheter, sterile Stopcock, sterile Surgical Drainage Tube, sterile Syringe, sterile Ureteral Stent and Catheter, sterile Urethral Pressure Profile Catheter, sterile Urological Catheter, Kit and Accessory, sterile Uterine Dilation Catheter and Device, sterile and non-sterile Vascular Catheter, Kit and Accessory

## CREATE MEDIC CO., LTD. Hokkaido Plant

12-49 Okayama-cho, Iwamizawa, Hokkaido, 079-0181 JAPAN

1. Production of sterile Anesthesia and Respiratory Tube, sterile Bladder Catheter and Kit, sterile Carotid Artery Shunt, sterile Cranial Drainage Tube, sterile Digestive Endoscopy Hood and Tube, sterile Dilator, sterile Embolectomy Catheter, sterile External Drainage Catheter, Kit and Accessory, sterile Gastrointestinal Tube and Kit, sterile Gastrointestinal Feeding Tube, Kits and Accessory, sterile Hysterosalpingography Catheter, Intermittent Self Catheter and Set, sterile Loop Fixture, sterile Nasal Wash Catheter, sterile Nephrostomy Catheter and Kit, sterile Non Vascular Guidewire, sterile Over Tube, sterile Puncture Needle, sterile Renal Cooling Catheter, sterile Respiratory Suction Tube, sterile Sengstaken Blakemore Tube, sterile Spinal Catheter, sterile Stabilizer for Catheter, sterile Stopcock, sterile Surgical Drainage Tube, sterile Syringe, sterile Ureteral Stent and Catheter, sterile Urethral Pressure Profile Catheter, sterile Urological Catheter, Kit and Accessory, sterile Uterine Dilation Catheter and Device, sterile and non-sterile Vascular Catheter, Kit and Accessory

2. Distribution of sterile Anesthesia and Respiratory Tube, sterile Assisted Reproduction Catheter, sterile Bladder Catheter and Kit, sterile Carotid Artery Shunt, sterile Cranial Drainage Tube, sterile Digestive Endoscopy Hood and Tube, sterile Dilator, sterile Electric Scalpel Cleaner, sterile Embolectomy Catheter, sterile External Drainage Catheter, Kit and Accessory, sterile Gastrointestinal Tube and Kit, sterile Gastrointestinal Feeding Tube, Kit and Accessory, sterile and non-sterile Hysterectomy Assisting Device, sterile Hysterosalpingography Catheter, sterile Infusion Device, Intermittent Self Catheter and Set, sterile Loop Fixture, sterile Nasal Wash Catheter, sterile Nephrostomy Catheter and Kit, sterile Non Vascular Guidewire, sterile Oesophageal Dilation Catheter, sterile Over Tube, sterile Puncture Needle, sterile and non-sterile Rectography Tube and Accessory, sterile Renal Cooling Catheter, sterile Respiratory Suction Tube, sterile Sengstaken Blakemore Tube, sterile Spinal Catheter, sterile Stabilizer for Catheter, sterile Stopcock, sterile Surgical Drainage Tube, sterile Syringe, sterile Ureteral Stent and Catheter, sterile Urethral Pressure Profile Catheter, sterile Urological Catheter, Kit and Accessory, sterile Uterine Dilation Catheter and Device, sterile and non-sterile Vascular Catheter, Kit and Accessory

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## Facility(ies):

### CREATE MEDIC CO., LTD. Mito Distribution Center

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

Distribution of sterile Anesthesia and Respiratory Tube, sterile Assisted Reproduction Catheter, sterile Bladder Catheter and Kit, sterile Carotid Artery Shunt, sterile Cranial Drainage Tube, sterile Digestive Endoscopy Hood and Tube, sterile Dilator, sterile Electric Scalpel Cleaner, sterile Embolectomy Catheter, sterile External Drainage Catheter, Kit and Accessory, sterile Gastrointestinal Tube and Kit, sterile Gastrointestinal Feeding Tube, Kit and Accessory, sterile and non-sterile Hysterectomy Assisting Device, sterile Hysterosalpingography Catheter, sterile Infusion Device, Intermittent Self Catheter and Set, sterile Loop Fixture, sterile Nasal Wash Catheter, sterile Nephrostomy Catheter and Kit, sterile Non Vascular Guidewire, sterile Oesophageal Dilation Catheter, sterile Over Tube, sterile Puncture Needle, sterile and non-sterile Rectography Tube and Accessory, sterile Renal Cooling Catheter, sterile Respiratory Suction Tube, sterile Sengstaken Blakemore Tube, sterile Spinal Catheter, sterile Stabilizer for Catheter, sterile Stopcock, sterile Surgical Drainage Tube, sterile Syringe, sterile Ureteral Stent and Catheter, sterile Urethral Pressure Profile Catheter, sterile Urological Catheter, Kit and Accessory, sterile Uterine Dilation Catheter and Device, sterile and non-sterile Vascular Catheter, Kit and Accessory

### CREATE MEDIC CO., LTD. Kyushu Distribution Center

2-52 Makiyamakaigan, Tobata-ku, Kitakyushu, Fukuoka, 804-0077 JAPAN

Distribution of sterile Anesthesia and Respiratory Tube, sterile Assisted Reproduction Catheter, sterile Bladder Catheter and Kit, sterile Carotid Artery Shunt, sterile Cranial Drainage Tube, sterile Digestive Endoscopy Hood and Tube, sterile Dilator, sterile Electric Scalpel Cleaner, sterile Embolectomy Catheter, sterile External Drainage Catheter, Kit and Accessory, sterile Gastrointestinal Tube and Kit, sterile Gastrointestinal Feeding Tube, Kit and Accessory, sterile and non-sterile Hysterectomy Assisting Device, sterile Hysterosalpingography Catheter, sterile Infusion Device, Intermittent Self Catheter and Set, sterile Loop Fixture, sterile Nasal Wash Catheter, sterile Nephrostomy Catheter and Kit, sterile Non Vascular Guidewire, sterile Oesophageal Dilation Catheter, sterile Over Tube, sterile Puncture Needle, sterile and non-sterile Rectography Tube and Accessory, sterile Renal Cooling Catheter, sterile Respiratory Suction Tube, sterile Sengstaken Blakemore Tube, sterile Spinal Catheter, sterile Stabilizer for Catheter, sterile Stopcock, sterile Surgical Drainage Tube, sterile Syringe, sterile Ureteral Stent and Catheter, sterile Urethral Pressure Profile Catheter, sterile Urological Catheter, Kit and Accessory, sterile Uterine Dilation Catheter and Device, sterile and non-sterile Vascular Catheter, Kit and Accessory

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