



America

CERTIFICATE

No. QS6 045257 0046 Rev. 01

Certificate Holder:

Cook Incorporated
750 Daniels Way
Bloomington IN 47404
USA

Certification Mark:



Scope of Certificate:

See Pages 2-3 for Overall Scope Statement.

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID:

F005468

Effective Date:

2022-05-27

Expiry Date:

2025-04-30

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Date of Issue: 2022-06-23

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services

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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Overall Scope Statement:

Design and Manufacture of Reusable and Disposable Diagnostic and Interventional Medical Devices (including Wire Guides, Cardiac Catheters, Visceral Catheters, Access Sets, Dilators, Dilation Sets, Catheter Introducers and Sets, Cannulas, Needles and Needle Sets, Pneumothorax Devices, Angioplasty Devices, Balloon Catheters, Drainage Access Sets, Stents and Stent Sets, Uroradiology Devices, Gastroenterology Devices, Intravascular Retrieval Devices, Embolization and Occlusion Devices, Infusion Catheters and Sets, Breast Lesion Localization Devices, Hysterosalpingography Devices, Lymphangiography and Sialography Devices, Vena Cava Filters and Sets, Oncology Devices, Central Venous Catheters and Sets, Arterial Catheters and Sets, Parenteral Nutrition Devices, Dialysis Devices and Sets, Emergency Medicine Devices, Centesis and Drainage Devices, Respiratory Management Devices,

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Surgical Instruments, Hernia Repair Sets, Endovascular Stent Grafts, Suture Sets, Stopcocks and Fittings, Ventricular Drainage Catheter Sets including Antibiotic Coated Sets, Bone Cement, Cement Dispenser, Vertebroplasty Sets and Ancillary Devices, Antibiotic Coated Catheter Sets, Pressure Monitoring Central Venous and Atria Sets including Heparin Coated Sets, Vessel Measuring Devices, Cerebral Catheters, Transjugular Sets, Vascular Closure Devices, Aspiration Catheters, Diagnostic Catheters and Devices, Sterile Non-Invasive Devices)

Facility(ies):

Cook Incorporated
750 Daniels Way, Bloomington IN 47404, USA

Cook Incorporated
1700 Curry Pike, Bloomington IN 47404, USA

Cook Incorporated
1100 West Morgan Street, Spencer IN 47460, USA

Cook Incorporated Ellettsville West
6600 McNeeley, Ellettsville, IN 47429, USA

Facility Scopes:

Cook Incorporated
750 Daniels Way, Bloomington IN 47404, USA

Design and Manufacture of Reusable and Disposable Diagnostic and Interventional Medical Devices (including Wire Guides, Cardiac Catheters, Visceral Catheters, Access Sets, Dilators, Dilation Sets, Catheter Introducers and Sets, Cannulas, Needles and Needle Sets, Pneumothorax Devices, Angioplasty Devices, Balloon Catheters, Drainage Access Sets, Stents and Stent Sets, Uroradiology Devices, Gastroenterology Devices, Intravascular Retrieval Devices, Embolization and Occlusion Devices, Infusion Catheters and Sets, Breast Lesion Localization Devices, Hysterosalpingography Devices, Lymphangiography and Sialography Devices, Vena Cava Filters and Sets, Oncology Devices, Central Venous Catheters and Sets, Arterial Catheters and Sets, Parenteral Nutrition Devices, Dialysis Devices and Sets, Emergency Medicine Devices, Centesis and Drainage Devices, Respiratory Management Devices, Surgical Instruments, Hernia Repair Sets, Endovascular Stent Grafts, Suture Sets,



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Stopcocks and Fittings, Ventricular Drainage Catheter Sets including Antibiotic Coated Sets, Bone Cement, Cement Dispenser, Vertebroplasty Sets and Ancillary Devices, Antibiotic Coated Catheter Sets, Pressure Monitoring Central Venous and Atria Sets including Heparin Coated Sets, Vessel Measuring Devices, Cerebral Catheters, Transjugular Sets, Vascular Closure Devices, Aspiration Catheters, Diagnostic Catheters and Devices, Sterile Non-Invasive Devices)
REPs Facility ID: F005468

Cook Incorporated

1700 Curry Pike, Bloomington IN 47404, USA

Receiving, Inspection, and Storage of Materials and Device Components; Final Packaging and Labeling Operations for Beacon Tip Catheters

REPs Facility ID: F005468

Cook Incorporated

1100 West Morgan Street, Spencer IN 47460, USA

Design and Manufacture of Reusable and Disposable Diagnostic and Interventional Medical Devices, Access Sets, Dilators, Dilation Sets, Needles and Needle Sets, Balloon Catheters, Drainage Access Sets, Stents and Stent Sets, Hysterosalpingography Devices, Stopcocks and Fittings and Aspiration Catheters

REPs Facility ID: F005468

Cook Incorporated Ellettsville West

6600 McNeeley, Ellettsville, IN 47429, USA

Sub-Assembly for Cannulas and Provision of Ethylene Oxide Sterilization Services

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Medical and Health Services