



America

CERTIFICATE

No. QS2 045257 0047 Rev. 04

Certificate Holder:

Cook Incorporated
750 Daniels Way
Bloomington IN 47404
USA

Certification Mark:



Scope of Certificate:

See Page 2 for Overall Scope Statement.

Standard:

ISO 13485:2016

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.:

72166728

Effective Date:

2022-11-01

Expiry Date:

2025-04-30

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Date of Issue: 2022-11-23

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



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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, 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

Facility Scopes:

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,

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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, 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

1700 Curry Pike, Bloomington IN 47404, USA

Facility Scopes:

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

Facility(ies):

Cook Incorporated

1100 West Morgan Street, Spencer IN 47460, USA

Facility Scopes:

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, Aspiration Catheters, Laser Systems and Accessories

Facility(ies):

Cook Incorporated Ellettsville West

6600 McNeeley, Ellettsville, IN 47429, USA

Facility Scopes:

Needle Manufacture and Sub-Assembly Work

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Facility(ies):

Cook Incorporated Ellettsville North
6300 North Matthews Drive, Ellettsville, IN 47429, USA

Facility Scopes:

Sub-Assembly Work, and Ethylene Oxide Sterilization

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