

Certificate of Approval

This is to certify that the Management System of:

Cook, Incorporated

750 Daniels Way PO Box 489, Bloomington, IN, 47404, United States

has been approved by LRQA to the following standards:

ISO 13485:2016



Cliff Muckleroy

Issued by: Lloyd's Register Quality Assurance, Inc.

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 30 May 2019

Expiry date: 30 April 2022

Certificate identity number: 10195598

Original approval(s):

ISO 13485 – 2 May 2006

Approval number(s): ISO 13485 – 00016116

The scope of this approval is applicable to:

Design and manufacture of reusable and disposable diagnostic and interventional medical devices (including all product families listed on the attached certificate Schedule), provision of contract Ethylene Oxide Sterilization Services and associated laboratory services.



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Certificate Schedule

Certificate identity number: 10195598

Location

750 Daniels Way PO Box 489, Bloomington, IN,
47404, United States

Activities

ISO 13485:2016

Design and Manufacturing of Polyvinyl Alcohol Foam Embolization Particles, Wire Guides, Cardiac Catheters, Visceral Catheters, Access Sets, Dilators, Dilation Sets, Catheter Introducers & Sets, Needles & Needle Sets, Pneumothorax Devices, Angioplasty Devices, Balloon Catheters, Drainage Access Sets, Stents & Stent Sets, Uroradiology Devices, Gastroenterology Devices, Stone Removal Devices, Intravascular Retrieval Devices, Embolization & Occlusion Devices, Infusion Catheters & Sets, Breast Lesion Localization Devices, Hysterosalpingography Devices, Lymphangiography & Sialography Devices, Vena Cava Filters & Sets, Oncology Devices, Central Venous Catheters & Sets, Arterial Catheters & Sets, Parenteral Nutrition Devices, Dialysis Devices & Sets, Emergency Medicine Devices, Centesis & 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.



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Certificate Schedule

Certificate identity number: 10195598

Location	Activities
1100 West Morgan Street, Spencer, IN, 47460, United States	ISO 13485:2016 Manufacture of Pneumothorax Devices, Gastroenterology Devices, Hysterosalpingography Devices, Parenteral Nutrition Devices, Dialysis Devices and Sets, Respiratory Management Devices, Diagnostic Catheters and Devices, Sterile Non-Invasive Devices, Pressure Monitoring Central Venous & Atria Sets, Dilation Sets, Central Venous Catheters and Sets, Centesis and Drainage Devices, Catheter Introducer Sets, Dilators, Balloon Catheters, Drainage Catheters and Sets, Extraction Devices, Introducers/Access Sets, Irrigator/Aspirators, Biopsy Devices, Insemination/IVF Catheters, Urethral/Ureteral Stents & Catheters, Electrical Devices, Surgical Knives, Cervical Cerclage Devices, Needles, Laser Systems & Accessories, Nephrostomy/Suprapubic/Percutaneous Catheters & Sets, OB/GYN Measurement Devices, Urinary Tract Measurement/Urodynamic Devices, Intracorporeal Lithotripsy Devices & Accessories, Sterile Non-invasive Devices, Wire Guides, Patency Devices.
6600 McNeely Road, Ellettsville, IN, 47429, United States	ISO 13485:2016 Manufacture of Needles and Sub-Assembly work.
6300 North Matthews Drive, Ellettsville, IN, 47429, United States	ISO 13485:2016 Manufacture of Drug Eluting Stents, Sub-Assembly Work, and Ethylene Oxide Sterilization.
300 East Elm Street, Canton, Illinois, 61520, United States	ISO 13485:2016 Manufacture of Sub-Assemblies for Angiographic Catheters.



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Certificate Schedule

Certificate identity number: 10195598

Location	Activities
1700 Curry Pike, Bloomington, IN, 47404, United States	ISO 13485:2016 Receiving, Inspection, and Storage of Materials and Device Components. Final Packaging and Labeling Operations for Beacon Tip Catheters.



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