Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 18 04 33038 028

Digitally signed by Bunic Gheorghe
Date: 2021.12.31 11:21:47 EET
Reason: MoldSign Signature
Location: Moldova

Manufacturer: **Cook Ireland Limited**
O'Halloran Road
National Technology Park
Limerick
IRELAND

Facility(ies): Cook Ireland Limited
O'Halloran Road, National Technology Park, Limerick, IRELAND

Product Category(ies): **Disposable devices and accessories for use in vascular, urological, gastroenterological pulmonary procedures (class IIa and IIb) including catheters, introducers, wires and drainage sets, electrosurgical and non-active instruments, stents and stent grafts, needles and cannulae. Vascular stents and delivery systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 75942541

Valid from: 2018-06-19
Valid until: 2023-06-18

Date, 2018-06-13

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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