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www.zlg.de
ZLG-BS-244.10.08

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 045257 0042 Rev. 01

Manufacturer:

Cook Incorporated
750 Daniels Way
Bloomington IN 47404
USA

Product Category(ies):

Class IIb Products
Percutaneous Biliary Drainage Catheters and Sets
Percutaneous Abscess Drainage Catheters and Sets
Ureteral Stents
Percutaneous Nephrostomy Catheters and Sets
Ureteral Stent Sets
Percutaneous Multipurpose Drainage Catheters and Sets
Surgically Invasive Gastroenterology Sets
Intraosseous Access Needles
Balloon Expandable Stents
Percutaneous Gastroenterology Catheters
Harrison Fetal Bladder Stent Set
Urinary Tract Stents and Stent Sets
Laser System
Sialendoscopy Devices
Embolization Coil Systems
Laser Fibers
Class IIa Products
Vascular Wire Guides
Hi Wire Hydrophilic Wire Guides
Diagnostic Visceral Catheters
Catheterization Catheters and Sets
Angioplasty Balloon Catheters
Dilators
Entry/Access Needles
Biopsy/Access Needles
Introducer Sets-Standard
Pneumothorax and Pleural Sets
Stone Removal Sets
Percutaneous Drainage Catheter Needle Sets
Dilation Sets
Percutaneous Access Sets
Percutaneous Drainage Access Catheter Sets
Transjugular Sets
Percutaneous Cholangiography Catheters and Sets
Pressure Monitoring Arterial Sets
Peritoneal Lavage Sets
Anchoring Devices
Catheter Repair Sets
Respiratory Management Sets
Laproscopic Endobiliary Stent Systems
Subcutaneous Tunneling Devices
Urology Wire Guides
Percutaneous Peritoneal Dialysis & Hemofiltration Sets
Urinary Tract Catheters
Short Term Percutaneous/Nephrostomy Devices
Aspiration Infusion Needles
Dilators & Dilator Sets
Introducer/Access Devices
Manipulation/Removal Devices

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Wire Guides
Hemostasis Devices
Instillation/Aspiration Devices
Biopsy Tissue Sampling Devices & Trays
Patency Devices
Surgical Knives
Invasive Urinary Tract Measurement Devices
Invasive Dilators & Dilator Sets
Localize, Hold or Stabilize Devices
Class III Products
Five Lumen Central Venous Catheter Sets
Diagnostic Heart Catheters
Polyvinyl Alcohol Foam Embolization Particles
Occlusion Balloon Catheters
Diagnostic Cerebral Catheters
Specialty Introducer Sets
Parenteral Nutrition Central Venous Sets
Pericardiocentesis Drainage Sets
Pressure Monitoring Central Venous and Atria Sets
Intravascular Retrieval Sets
Intracardiac Devices
Transseptal Needles
Selective Infusion Delivery Devices Microcatheters
Abdominal Aortic Aneurysm Endovascular Stent Grafts

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. 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:G1 045257 0042 Rev. 01

Report No.: 1678588

Valid from: 2021-05-25
Valid until: 2024-05-26

Date, 2021-05-25

Christoph Dicks
Head of Certification/Notified Body

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