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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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**


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

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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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