



# 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  
Laparoscopic 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:G10452570042Rev.01](http://www.tuvsud.com/ps-cert?q=cert:G10452570042Rev.01)

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Christoph Dicks  
Head of Certification/Notified Body