COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

Manufacturer's Declaration of Conformity

No. 017-071-191104-8

Manufacturer's Name: Cook Incorporated
Manufacturer's Address: 750 Daniels Way
Bloomington, IN 47404; USA

Object of the Declaration: Technical File 017-071, Hemostasis Devices
(A complete listing of part numbers is attached)

Classification: **IIa, Rule 7**
Conformity Assessment Route: **Annex II.3**

The above Object of the Declaration fulfills the requirements of Council Directive 93/42/EEC of 14 June 1993, as amended by Council Directive 2007/47/EC of 5 September 2007, and is in conformity with the requirements of the following standards:

Standards	Title	Date of Issue
ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes	2016
EN ISO 14971	Medical devices – Application of risk management to medical devices	2012
BS EN ISO 11135	Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices	2014
EN 556-1/AC	Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices	2001/2006
EN ISO 11737-1/AC	Sterilization of medical devices – Microbiological methods – Part 1: Determination of the population of microorganisms on product	2006/2009
EN ISO 11737-2	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	2009
EN ISO 10993-1/AC	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	2009/2010
EN ISO 10993-3	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	2014
EN ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for vitro cytotoxicity	2009
EN ISO 10993-6	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation	2009
EN ISO 10993-7/AC	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals	2008/2009
EN ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity	2013
EN ISO 10993-11	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	2009
EN ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	2009
EN ISO 11607-2	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	2006
EN 1041	Information supplied by the manufacturer of medical devices	2008
EN ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements	2016

Digitally signed by Bunic Gheorghe
Date: 2019.11.19 23:00:55 CET
Reason: MoldSign Signature
Location: Moldova

Manufacturer's Declaration of Conformity

No. 017-071-191104-8

Notified Body:	TÜV SÜD (0123) Ridlerstraße 65 80339 Munich Germany
Certificate Number:	G1 045257 0042 Rev. 00
European Representative:	Cook Medical Europe Ltd O'Halloran Road National Technology Park Limerick, Ireland
Signed For and On behalf of:	Cook Incorporated
Signature:	Kris Weathers
Name:	Kris Weathers, BA, RAC
Position:	Regulatory Affairs Manager
Location:	Bloomington, IN, USA
Date:	04 November 2019

Manufacturer's Declaration of Conformity

No. 017-071-191104-8

Reorder Number	Product Name
086014	Kaye Nephrostomy Tamponade Catheter
086514	Kaye Nephrostomy Tamponade Catheter Stent Set
J-BUS-253000	Balloon Uterine Stent
J-BUS-404000	Balloon Uterine Stent
J-SOS-100500	Bakri Postpartum Balloon
J-SOSR-100500	Bakri Postpartum Balloon

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ZLG-BS-244.10.08

TÜV SÜD 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. 00

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
Percutaneous Biliary Stent Sets
Ureteral Stent Sets
Percutaneous Multipurpose Drainage Catheters and Sets
Surgically Invasive Peritoneal Dialysis Sets
Surgically Invasive Gastroenterology Sets
Intraosseous Access Needles
Balloon Expandable Stents
Percutaneous Gastroenterology Catheters
Long Term Percutaneous Nephrostomy and Suprapubic Cystostomy Drainage Devices
Foley Catheters - Specialty
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
Non-Vascular Wire Guides
Tip Deflecting Wire Guides
Diagnostic Visceral Catheters
Pleural Drainage Catheters
Catheterization Catheters and Sets
Lu Max Flex Guiding Catheters
Angioplasty Balloon Catheters
Dilators
Entry/Access Needles
Biopsy/Access Needles
Breast Lesion Localization Needles
Stiffening Cannulas
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

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

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No. G1 045257 0042 Rev. 00

Transjugular Sets
Percutaneous Cholangiography Catheters and Sets
Pressure Monitoring Arterial Sets
Peritoneal Lavage Sets
Anchoring Devices
Catheter Repair Sets
Respiratory Management Sets
Thoracentesis Drainage Sets
Laproscopic Endobiliary Stent Systems
Subcutaneous Tunneling Devices
Enteral Feeding Tubes
Urology Wire Guides
Percutaneous Peritoneal Dialysis & Hemofiltration Sets
Urinary Tract Catheters
Short Term Percutaneous/Nephrostomy Devices
Aspiration Infusion Needles
Dilators & Dilator Sets
Suture Devices
Introducer/Access Devices
Manipulation/Removal Devices
Wire Guides
Hemostasis Devices
Amniocentesis Tray/Amniocentesis Needle
Instillation/Aspiration Devices
Drainage Devices
Biopsy Tissue Sampling Devices & Trays
Patency Devices
Surgical Knives
Invasive Urinary Tract Measurement Devices
Invasive Dilators & Dilator Sets
Localize, Hold or Stabilize Devices
Endoscopic Devices

<u>Class III Products</u>
Five Lumen Central Venous Catheter Sets
Spectrum and Spectrum Glide
Central Venous Catheter Sets
Heparin Coated Pressure Monitoring Central Venous and Atria Sets
Diagnostic Heart Catheters
Embolization Devices
Polyvinyl Alcohol Foam Embolization Particles
Occlusion Balloon Catheters
Angiographic 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

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Transseptal Needles
Embolotherapy and / or Guiding Catheters
Selective Infusion Delivery Devices Microcatheters
Vena Cava Filter Sets
Central Venous Hemodialysis Sets
Vessel Measure Devices
Abdominal Aortic Aneurysm Endovascular Stent Grafts
Spinal Needles
Central Circulatory Wire Guides

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.: 72153312

Valid from: 2019-11-01
Valid until: 2024-05-26

Date, 2019-10-25

Stefan Preiß
Head of Certification/Notified Body

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