Lloyd's Register LRQA

Digitally signed by Bunic Gheorghe
Date: 2020.01.18 21:07:36 EET
Reason: MoldSign Signature
Location: Moldova

EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

Cook Incorporated
750 Daniels Way
Bloomington, Indiana 47404, USA

has been assessed against the requirements of Annex V of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

This certificate forms part of the approval identified by certificate number UQA 4000228

Certificate No:	4000228/C
Original Approval:	April 12, 2006
Current Certificate:	May 1, 2014
Certificate Expiry:	April 30, 2019

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

71 Fenchurch Street, London EC3M 4BS, United Kingdom
Macro Revision 13

Lloyd's Register
LRQA

EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE SYSTEM

CERTIFICATE 4000228/C SCHEDULE

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

Cook Incorporated
750 Daniels Way
Bloomington, Indiana 47404, USA

Class I Sterile

Torque Cables
Gastroenterology Catheters
Gastroenterology Balloon Catheters
Respiratory Management Catheters
Gastroenterology Sets
Esophageal Dilation Sets
Devices for Diagnostic Procedures through Body Orifices
Sterile Stopcocks, Fittings and Accessories
Connecting Tubes
Catheter Accessory Devices
Wire Guide Accessory Devices
Needle Accessory Devices
Sterile Syringes
Non-Vascular Dilation Balloon Catheters
External Gland Ductographic Devices
Urinary Tract Catheters
Urinary Tract Measurement Devices
Extractors
Occlusion Balloon Catheters
Body Orifice Introducer/Access
Dilator and Dilator Sets
Non-Invasive Devices & Accessories – Sterile
Intrauterine Insemination Devices
Biopsy Tissue Sampling Devices
Uterine Sounds
Cervical Cerclage Devices
IVF Pipettes
Flexipet Manipulation Denuding Tool
Vital Port Accessory Devices
Lead Extraction Accessory Devices
Doppler Extension Cable

Schedule Issue: Eight

Date of Schedule Issue: May 1, 2014

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 16 03 33038 018

Holder of Certificate: **Cook Ireland Limited**
O'Halloran Road
National Technology Park
Limerick
IRELAND

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

Certification Mark:

Scope of Certificate: **Design, Development, Production and Distribution of Obstetric / Gynaecological, Gastroenterological, Pulmonary, Urological, Vascular Devices and Accessories and Drug Eluting Peripheral Stents with Delivery Systems.**

Applied Standard(s):
EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 75933316

Valid from: 2016-06-01
Valid until: 2019-05-31

Date, 2016-05-24

Stefan Preiß

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00