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Manufacturer's Declaration of Conformity

No. 017-031-191104-5

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

Object of the Declaration: Technical File 017-031, Instillation/Aspiration Devices
(A complete listing of part numbers is attached)

Classification: **IIa, Rule 6**
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:

Standard	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 products	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 10993-5	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	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 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 SO 15223-1	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements	2016

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

Reorder Number	Product Name
090001-S9	Williams Cystoscopic Injection Needle
090001-S10	Williams Cystoscopic Injection Needle
090001-S26	Williams Cystoscopic Injection Needle
090001-S34	Williams Cystoscopic Injection Needle
090001	Williams Cystoscopic Injection Needle
PPN-2020	Periprostatic Injection Needle
PPN-2025	Periprostatic Injection Needle