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 18 04 33038 028

Digitally signed by Bunic Gheorghe
Date: 2021.12.14 09:26:04 AZOT
Reason: MoldSign Signature
Location: Moldova

Manufacturer:

Cook Ireland Limited
O'Halloran Road
National Technology Park
Limerick
IRELAND

Facility(ies):

Cook Ireland Limited
O'Halloran Road, National Technology Park, Limerick, IRELAND

Product Category(ies):

Disposable devices and accessories for use in vascular, urological, gastroenterological pulmonary procedures (class IIa and IIb) including catheters, introducers, wires and drainage sets, electrosurgical and non-active instruments, stents and stent grafts, needles and cannulae. Vascular stents and delivery systems

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.: 75942541

Valid from: 2018-06-19
Valid until: 2023-06-18

Date, 2018-06-13

Stefan Preiß

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