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

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 17 10 74222 008

Manufacturer:

Creagh Medical Ltd
IDA Business Park
Ballinasloe, Co Galway, H53 K8P4
IRELAND

Facility(ies):

Creagh Medical Ltd
IDA Business Park, Ballinasloe, Co Galway, H53 K8P4, IRELAND

Product Category(ies):

PTA Catheters for peripheral applications

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.: 75940463

Valid from: 2017-10-27
Valid until: 2022-10-22

Date, 2017-10-27

Stefan Preiß

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