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 04 53268 071

Manufacturer:

RAUMEDIC AG
Hermann-Staudinger-Strasse 2
95233 Helmbrechts
GERMANY

Facility(ies):

RAUMEDIC AG
Hermann-Staudinger-Strasse 2, 95233 Helmbrechts, GERMANY

RAUMEDIC AG
Crailsheimer Strasse 34, 91555 Feuchtwangen, GERMANY

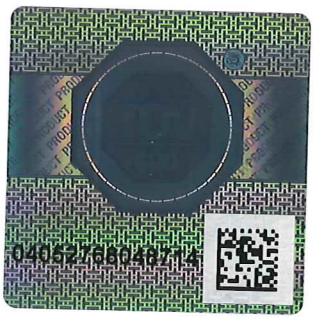
Product Category(ies):

Tubings, components, tubing systems, catheters including accessories (see attachment)

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.: 713102851-2

Valid from: 2017-07-11
Valid until: 2022-07-10



Date, 2017-06-29

Stefan Preiß

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

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Product Service

Attachment for Certificate no G1 17 04 53268 071
valid from 2017-07-11

Product Groups:	**Class**
Spliceable Tunneling Sleeve – application accessory	IIa
Conventional Ventricular Catheter – for use in Neurosurgery	III
ECC tubing and connectors – for extracorporeal circulation (used for assembly of tube sets for the heart-lung machine)	IIa

Munich, MHS-CRT, 2017-06-29

Stefan Preiß

HAMBURG TÜV SÜD PRODUCT SERVICE

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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