Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 005176 0002 Rev. 01

Manufacturer: **Andramed GmbH**
Schießwieslenstr. 18
72766 Reutlingen
GERMANY

Facility(ies): Andramed GmbH
Schießwieslenstr. 18, 72766 Reutlingen, GERMANY

Product Category(ies): **peripheral stents, catheter introducers, retrieval baskets, PTA balloon catheters, valvulotomes**

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.: 713164002

Valid from: 2019-08-04
Valid until: 2024-05-26

Date, 2019-08-02

Stefan Preiß
Head of Certification/Notified Body

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