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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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TÜV SÜD 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 104068 0002 Rev. 00

Manufacturer:

SCW Medicath Ltd.
No.4, Baolong 6th Road
Baolong Industrial Town
Longgang District
518116 Shenzhen, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Hydrophilic Guidewire

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.: GZ1942701

Valid from: 2020-01-07
Valid until: 2024-05-26

Date, 2020-01-07

Christoph Dicks
Head of Certification/Notified Body

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

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No.4, Baolong 6th Road, Baolong Industrial Town, Longgang District, 518116 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA

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