DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 104068 0001 Rev. 00

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

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

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Hydrophilic Guidewire**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: GZ1942701

Valid from: 2020-01-07
Valid until: 2023-01-06

Date, 2020-01-07

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV®

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

SCW Confidential 保密文件 益心达