





Product Service

# Supplement to Quality System Certificate

No. SUP 104068 0004 Rev. 00

**This supplement is only valid in conjunction with the main certificate:** **Q8 104068 0003 Rev. 00**

**Certificate Holder:** **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

The quality system certified as stated in the main certificate additionally fulfills the applicable requirements of

EN ISO 11135:2014 "Sterilization of health-care products - Ethylene oxide - requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)"

**Audit Report:** GZ2042701

**Dated:** 2020-06-08

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization

**Valid from:** 2020-06-17

Christoph Dicks  
Head of Certification/Notified Body