



Certificate

No. Q8 104068 0003 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

SCW Medicath Ltd.

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

OF CHINA



Provision of ETO Sterilization Service for Scope of Certificate:

Single-Used Medical Device

EN ISO 13485:2016 Applied Standard(s):

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.:

Valid from: 2020-06-16 Valid until: 2023-01-06

2020-06-16 Date,

Christoph Dicks

Head of Certification/Notified Body

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

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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 - equirements for the development, validation and routine control of a sterilization process for medical

devices (ISO 11135:2014)"

Audit Report: Dated:

GZ2042701 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:

Christoph Dicks

Head of Certification/Notified Body