



Certificate

No. Q5 063196 0018 Rev. 00

Holder of Certificate: **Shenzhen Hexin ZONDAN Medical Equipment Co., Ltd.**
Floor 14, Block D
Dianlian Technology Building
the Crossing between South Circle Road and South Fuli Road
Guangming District
518106 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Shenzhen Hexin ZONDAN Medical Equipment Co., Ltd.
Floor 14, Block D, Dianlian Technology Building, the Crossing
between South Circle Road and South Fuli Road, Guangming
District, 518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Pulse Oximeter, Patient Monitor, Fetal Dopplers, Fetal Monitor**

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 063196 0018 Rev. 00

Report No.: SH2022301
Valid from: 2021-04-30
Valid until: 2024-04-10

Date, 2021-04-30

Christoph Dicks
Head of Certification/Notified Body