







Certificate

No. Q5 032913 0042 Rev. 04

Holder of Certificate: Ningbo David Medical

Device Co., Ltd.

No.2, Keyuan Road

Shipu Science and Technology Park, Xiangshan

315731 Ningbo, Zhejiang Province PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development, Production and Distribution

of Infant Incubator, Transport Incubator, Infant Radiant Warmer, Neonate Bilirubin Phototherapy Equipment, Far-Infrared Radiant Heater, Low-Pressure Aspirator, Breath Resuscitation Bag, Infant Non-contact Oxygen

Hood, Infant Bed, Infant Head Fixing Unit,

Medical Air/Oxygen Blender, Infant T-piece Resuscitator,

Medical Air Compressor, Patient Monitor, Transcutaneous Jaundice Detector,

Neonate Hypothermia Device, EEG Monitor, Medical Heater, Nitric Oxide Flow Controller

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5-032913-0042 Rev. 04

Report No.: SH2501101

 Valid from:
 2025-06-01

 Valid until:
 2028-05-31

Christoph Dicks

Head of Certification/Notified Body

Date, 2025-03-31









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Applied Standard(s): ISO 13485:2016

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -

Requirements for regulatory purposes

Facility(ies): Ningbo David Medical Device Co., Ltd.

No.2, Keyuan Road, Shipu Science and Technology Park, Xiangshan, 315731 Ningbo, Zhejiang Province, PEOPLE'S

REPUBLIC OF CHINA

See Scope of Certificate