





## Certificate

No. Q5 032913 0042 Rev. 01

**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:** 



Design and Development, Scope of Certificate:

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

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 032913 0042 Rev. 01

SH2201101 Report No.:

Valid from: 2022-07-01 Valid until: 2025-05-31

2022-07-01 Date.

Head of Certification/Notified Body



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No. Q5 032913 0042 Rev. 01

EN ISO 13485:2016 Applied Standard(s):

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

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

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

REPUBLIC OF CHINA

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** 

Ningbo David Medical Device Co., Ltd.

No.35, Jinxing Road, Binhai Industrial Park, Xiangshan Economic Development Zone, 315712 Ningbo, Zhejiang, PEOPLE'S

REPUBLIC OF CHINA

Storage 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**