ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 032913 0046 Rev. 00

Manufacturer:

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

SRN Manufacturer - CN-MF-000009962

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 032913 0046 Rev. 00

Report No.: SH2201102

Valid from: 2024-03-01
Valid until: 2029-02-28

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-03-01

Digitally signed by Lungu Ion
Date: 2025.10.20 09:35:31 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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(Class IIa and Class IIb Devices)

No. G10 032913 0046 Rev. 00

Classification:	Class IIb
Device Group:	Z120804 - NEONATOLOGY INSTRUMENTS
Intended Purpose:	Intended to provide a clean-air, temperature-appropriate incubation and therapeutic environment for low-birth-weight infants, invalid infants and preterm infants, and to help medical institutions to transfer infants safely.

Classification:	Class IIb
Device Group:	Z120804 - NEONATOLOGY INSTRUMENTS
Intended Purpose:	Intended to provide a controlled environment for premature and invalidism infants to grow up.

Classification:	Class IIb
Device Group:	Z120804 - NEONATOLOGY INSTRUMENTS
Intended Purpose:	Intended to provide a controlled environment for premature and invalidism infants to grow up, also can provide an open type environment to nursing or saving the neonatal infant's life and adjust the infant's temperature.

Classification:	Class IIb
Device Group:	Z120804 - NEONATOLOGY INSTRUMENTS
Intended Purpose:	Intended to provide an open type environment to nursing or saving the neonatal infant's life and adjust the infant's temperature.

Classification:	Class IIa
Device Group:	Z12080401 - PAEDIATRIC PHOTOTHERAPY EQUIPMENT Z12080410 - TRANSCUTANEOUS BILIRUBINOMETERS
Intended Purpose:	—

The validity of this certificate depends on conditions and/or is limited to the following: —

Revision History:

Rev.	Dated	Report	Description
00	2024-03-01	SH2201102	Initial issuance

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