



## EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A  
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

**No. G21 074340 0020 Rev. 00**

### Manufacturer:

**HONSUN (NANTONG) Co., Ltd.**

No.8 Tongxing Road  
Economic&Technological  
Development Area  
226009 Nantong City  
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000009428

### 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 XI Part A of this regulation with a positive result.

As applicable the involvement of the notified body is limited to the aspects relating to:

- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. 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:G21\\_074340\\_0020\\_Rev.00](http://www.tuvsud.com/ps-cert?q=cert:G21_074340_0020_Rev.00)

**Report No.:** SH2261802

**Valid from:** 2024-02-23

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**Issue date:** 2024-02-23

Christoph Dicks  
Head of Certification/Notified  
Body



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



Product Service

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**Classification:** Class I  
**Device Group:** C9006 - ANEROID SPHYGMOMANOMETERS  
**Device Properties:** MDS 1010 - Devices with a measuring function

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

### Revision History:

Rev.	Dated	Report	Description
00	2024-02-23	SH2261802	Initial issuance