

Manufacturer: HONSUN (Nantong) Co., Ltd.

SRN number: CN-MF-000009428

Address: No.8, Tongxing Road, Economic&Technical Development Area,
Nantong City, Jiangsu, P.R.China

EU representative: Shanghai International Holding Corp. GmbH (Europe)

SRN number: DE-AR-000000001

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product: Aneroid Sphygmomanometer

Intended use: Aneroid Sphygmomanometer is a non-automated, mechanical blood-pressure monitor that used for the indirect measurement (noninvasive) and display of arterial blood pressure.

ENDN code: C9006

Model Code: See product list

Product picture: See the *NTLD-EC-02 Product introduction*

Classification: Class I (MDR, Annex VIII Rule 1)

Basic UDI-DI: 697038425ASMR8

Conforming Assessment Route :Annex IX

We herewith declare that the above mentioned products meet the provisions of the following EC Council Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

Regulations

General applicable regulation: Medical Device Regulation: (EU)2017/745.

Common standards applied: see *NTLD-EC-05 Standard list*

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr, 65, 80339 München,
Germany

Certificate: No. G21 074340 0020 Rev.00

Expiration date of the Certificate: 2029-02-22

Date CE mark was affixed: start of CE marking lot: 2010-07

Identifier of Notified Body: CE0123



HONSUN (NANTONG) CO., LTD

Delcaration of conformity

CE technical file - ANEROID SPHYGMOMANOMETER

No. NTLD-EC-01

Revision: D/3

Effective: 2025.3.6

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Signature:

Position: PRRC(Person responsible for regulatory compliance)

Place, Date: NANTONG, 2025.3.6

Product list:

Name	Model
Aneroid Sphygmom anometer	HS-20A/HS-20D/HS-20E/HS-20F/HS-2000/HS-20C/HS-20G/HS-20H/ HS-100/HS-100A
	HS-50A/HS-50C/HS-50D/HS-50B/HS-50E
	HS-201M/HS-201E/HS-201S/HS-201T/HS-201W/HS-201X/HS-201Y/ HS-201Z/HS-201A/HS-201C/HS-201J/HS-201K/HS-201Q/HS-201D/ HS-201DT/HS-201A2/HS-201B2/HS-201Q3/HS-201M/HS-201C2/HS- 201Q2/HS-GF-301/HS-GF-302/HS-GF-303
	HS-60A/HS-60C/HS-60D/HS-60F/HS-60E/HS-70A/HS-70B/HS-70C/ HS-70D/HS-70E/HS-70F