

**HONSUN (NANTONG) CO., LTD**

Declaration of conformity

CE Technical File- ANEROID SPHYGMOMANOMETER

No.	NTLD-EC-01
Revision:	D/1
Effective:	2023.03.29
Page:	Page 1 of 2

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.

EMDN code: C9006

Model Code: See product list

Product Picture: See the *NTLD-EC-01 Device description and specification*

Basic UDI-DI: 697038425ASMR8

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

Conforming Assessment Route: Annex XI

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 and the notified body. We are exclusively responsible for the Declaration of Conformity.

Regulations

Medical Device regulation: COUNCIL 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 : 2006-07

Identifier of Notified Body: CE0123



HONSUN (NANTONG) CO., LTD

Declaration of conformity

CE Technical File- ANEROID SPHYGMOMANOMETER

No. NTLD-EC-01

Revision: D/1

Effective: 2023.03.29

Page: Page 2 of 2

Signature:

Position: PRRC(Person responsible for regulatory compliance)

Place, Date: NANTONG, 2023-03

Product list

NAME	EMDN Codes	Model No.
Aneroid Sph ygmomano meter	C9006	HS-20A/HS-20D/HS-20E/HS-20F/HS-50A/HS-50C/HS-50D/HS-50B/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/Mobi/HS-60A/HS-60D/HS-60F/HS-70A