DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-C9005-01.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Digitally signed by Potînga Stela
Date: 2025.04.22 16:48:17 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Manufacturer

Name: WENZHOU KANGSHUN MEDICAL DEVICES CO.,LTD
Address: No.706, Yanyun Road, Lingkun Street, Oujiang Estuary Industrial District, Wenzhou, Zhejiang Province, postcode 325011.

Product Information

Name : STETHOSCOPE
Model KS-2035,KS-2045,KS-2015,KS-2055, KS-2026,KS-2027,KS-2025,KS-2026B,ks-2032A CM-4111,CM-4113,CM-4252,CM-4158,CM-4136
UMDNS Code : 13750
Basic UDI-DI : 697518547StethoscopesYD
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: shengguang wu Date:2022/02/26

Position: GM Place: Wenzhou/China