TÜVRheinland®

CE Technical Documentation Review Report

Manufacturer:	**Wenzhou Kangshun Medical Devices Co., Ltd.** Xitai Village, Zhuangyuan Town, Longwan District, Wenzhou, Zhejiang Province 320511, China
Report Number:	15079788 001
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII
Product(s):	Stethoscopes
Type(s)/Model(s):	Single Head Stethoscope series Dual-head Stethoscope series Multifunctional Stethoscope series Stainless steel Stethoscope series
Classification:	Class I, rule 1 (according to manufacturer's declaration)
Review result:	During the examination of the provided Technical Documentation (No.: KS-01, Revision A/0, Date 2014-12-10), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

TÜV Rheinland (Shanghai) Co., Ltd.

Shanghai, 2021-03-08

Digitally signed by Potinga Stela
Date: 2022.11.21 13:58:59 EET
Reason: MoldSign Signature
Location: Moldova

Daniel ZHU
Lead Auditor, Product Assessor
Medical Device Services

Products Quality Assurance TÜVRheinland® Approved

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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.

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