

## 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.

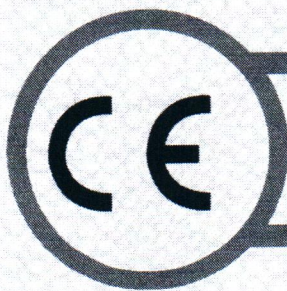
Shanghai, 2021-03-03

TÜV Rheinland (Shanghai) Co., Ltd.



Daniel ZHU  
Lead Auditor, Product Assessor  
Medical Device Services





## 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

