



DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745



Manufacturer: Ningbo UNIMED Medical Instrument Co., Ltd.
Address: 26 Laoshan Road, Beilun, Ningbo, China.
EC Representative: SUNGO Europe B.V.
Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands
Product Name: Stethoscope
Model: [SF100, SF101, SF207, SF208, SF402, SF500, SF601, SF701, SF702, SF200, SF201, SF202, SF203, SF205, SF306, SF411, SF412, SF413, SF501, SF502, SF503, SF504, SF507, SF508, SF512, SF513, SF602, SF603, SF5234, SF301, SF302, SF303, SF304, SF305.]
Classification: Class I
Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745
Conformity Assessment Annex II+III of Regulation (EU) 2017/745
Procedure:
SRN: CN-MF-000009819
Basic UDI-DI: 697454646STETHOSCOPEJV

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

EN ISO 14971:2019 EN ISO 15223-1:2021 EN ISO 20417:2021

Signature: 

Name / Position: Zheng hui/ GM

Date: 

Place: Ningbo / China

[Doc. No.: CE-MDR-01-02 Rev. A/0]