



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: Olympisch Stadion 24, 1076DE Amsterdam, 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: /

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 14971:2012 EN ISO 15223-1:2016 EN 1041:2008+A1:2013

Signature:

Name / Position: Zheng hui / GM

Date:

Place: Ningbo / China

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