DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

Name: LOTUS NL B.V.
Address: Koningin Julianaplein 10, leVerd.2595AA, The Hague, Netherlands.
SRN: NL-AR-000000121

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-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: Wuxi Exanovo Medical Instrument Co.,Ltd.
Address: C2-LianDong U Gu，Xibei Town，Xishan District，Wuxi 214194 Jiangsu，P.R.China.
SRN:CN-MF-000021396

Product Information

Name：Stethoscope
Model：MC-220、MC-230、MC-410、MC-510、MC-210、MC-500
EMDN：C9005
GMDN: 13755
Basic UDI-DI：69706910MC002KU
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: Date: Apr.12.,2023

WUXI EXANOVO MEDICAL INSTRUMENT CO.,LTD.

Liuyang Xiao

Position: GM Place: Wuxi / China