EU Declaration of Conformity

Manufacturer	:	Rossmax Swiss GmbH
Address		Widnauerstrasse 1, CH-9435 Heerbrugg, Switzerland
SRN	:	CH-MF-000011245
Representative in Europe	:	CMC Medical Devices& Drugs S.L.
Address		C/ Horacio Lengo No 18, CP 29006, Málaga, Spain
Basic UDI-DI	:	4715139StethoscopeVM
Product name	:	Stethoscope
Product code	:	EB100, EB200, EB500, EB600, ST-CARD-002, ST-DH-002, ST-SH-001, ST-SR-001
Conformity Assessment	:	Regulation (EU) 2017/745 of the European Parliament and of the Council ANNEX II, ANNEX III, ANNEX IV
Classification	:	Class I (According to g Regulation (EU) 2017/745, Annex VIII, Rule 1)
Lot No.	:	YY M P XX

- XX → Sequential number
- P → Internal number
- M → Manufacturing month.
- YY → Manufacturing year.

The above-mentioned devices are in full compliance with the relevant provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council, Annex I-General Safety and Performance Requirements and applied harmonized standards, national standards or other normative documents and, if applicable, common specification.

EN ISO 14971:2019, EN1041:2008, EN ISO15223-1:2021, EN ISO 13485:2016

Rossmax Swiss GmbH is exclusively responsible for the declaration of conformity.

This declaration is limited by the issuing of a revised declaration of conformity after change of the product.

Digitally signed by Neer Ghennadii
Date: 2023.03.01 13:54:41 EET
Reason: MoldSign Signature
Location: Moldova

Yolanda Lin

Signature: **Yolanda Lin, Management Representative**

Date: Feb. 20, 2023