

EU Declaration of Conformity

Doc No.	RD-4-136
Version	Α
Page	1/1
Effective Date	2021/6/2

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

Sequential number

Internal number

Manufacturing month.

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.

Yolarda lin

Signature: Yolanda Lin, Management Representative

Date: Feb. 20, 2023