



EU Declaration of Conformity

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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	: 4715139ProbecoverY6
Product name	: Probe cover for ear thermometer
Product code	: P1, P2
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 5)

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 15223-1:2021; EN 1041:2008; EN ISO 10993-1:2009/ AC2010; EN ISO 10993-5:2009; EN ISO 10993-10: 2013

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.

Signature: Yolanda Lin, Management Representative

Date: Feb. 20, 2023