



## EC Declaration of Conformity

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| Version        | I          |
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| Effective Date | 2014/02/14 |

### 1. EC Declaration of Conformity

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|--|---|
| <b>Manufacturer</b><br>Address                           | : Rossmax Swiss GmbH<br>Widnauerstrasse 1, CH-9435 Heerbrugg, Switzerland   |
| <b>Notified Body</b><br>Address<br>EU Identification No. | : SGS Belgium NV<br>SGS House Noorderlaan 87 2030 Antwerp Belgium<br>1639   |
| Certificate No.  | : TW19/20056  |
| <b>Representative in Europe</b><br>Address               | : CMC Medical Devices & Drugs S.L.<br>C/ Horacio Lengo No 18, CP 29006, Málaga, Spain   |
| <b>Product type</b>                                      | : Infrared Ear Thermometer  |
| <b>Type Designation</b>                                  | : RA600, RB600  |
| <b>Conformity Assessment</b>                             | : EU Council Directive 93/42/EEC amended by 2007/47/EC Annex II (excluding Section 4) and Regulation (EU) 2023/607 amendment of Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices  |
| <b>Classification</b>                                    | : Class IIa (According to EU Council Directive 93/42/EEC amended by 2007/47/EC, Annex IX, Rule 10)  |
| <b>Lot No.</b>   | : <u>YY M XXX</u><br><pre>graph TD     A[YY M XXX] --&gt; B[YY]     A --&gt; C[M]     A --&gt; D[XXX]     B --&gt; B1[Manufacturing year.]     C --&gt; C1[Manufacturing month.]     D --&gt; D1[Lot sequential number]</pre> |

The above-mentioned devices are in full compliance with the relevant provisions of EU Council Directive 93/42/EEC amended by 2007/47/EC, Regulation (EU) 2023/607 amendment of Regulations (EU) 2017/745, Annex I-Essential Requirements and applied harmonized standards, national standards or other normative documents.

EN ISO 15223-1: 2016, EN 1041: 2008, EN12470-5:2003, EN ISO 10993-1:2009/ AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 14155:2011, EN ISO 13485:2016, EN ISO 14971:2019, EN 60601-1:2006/ A1 :2013, EN 60601-1-2:2015, EN62304:2006/ AC2008, EN 60601-1-6:2010, EN62366:2008, EN60601-1-11: 2015

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 and/or the expiration date (31.12.2028) of the certificate of 93/42/EEC.

*Yolanda Lin*

Signature: **Yolanda Lin, Management Representative**

Date: Mar. 07, 2024