

Doc No.	RD-4-002
Version	I
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Effective Date	2014/02/14

## 1. EC Declaration of Conformity

<b>Manufacturer</b>	: Rossmax Swiss GmbH
<b>Address</b>	: Widnauerstrasse 1, CH-9435 Heerbrugg, Switzerland
<b>Notified Body</b>	: SGS Belgium NV
<b>Address</b>	: SGS House Noorderlaan 87 2030 Antwerp Belgium
<b>EU Identification No.</b>	: 1639
<b>Certificate No.</b>	: TW19/20056
<b>Product type</b>	: Non-Invasive Blood Pressure Measuring Device with pulse arrhythmia detecting function (including Afib( Atrial Fibrillation), PC(Premature Contraction), TACH(Tachycardia) and BRAD (Bradycardia)
<b>Type Designation</b>	: X5, C5, Z5
<b>Conformity Assessment</b>	: EU Council Directive 93/42/EEC amended by 2007/47/EC Annex II (excluding Section 4)
<b>Classification</b>	: Class IIa (According to EU Council Directive 93/42/EEC amended by 2007/47/EC, Annex IX, Rule 10)
<b>Serial No.</b>	: <u>YY M 001 - 000001</u> <div style="margin-left: 40px;"> <span style="margin-left: 100px;">→ Sequential number</span>  <span style="margin-left: 100px;">→ Lot sequential number</span>  <span style="margin-left: 100px;">→ Manufacturing month.</span>  <span style="margin-left: 100px;">→ Manufacturing year.</span> </div>

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

EN ISO 15223-1: 2016, EN 1041: 2008, EN 1060-1:1995+A2:2009, EN 1060-3:1997+A2:2009, EN 1060-4:2004, 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 14971:2012, EN 60601-1:2006/ A1 :2013, EN 60601-1-2:2015, EN62304:2006/ AC2008, EN 60601-1-6:2010, EN62366:2008, EN60601-1-11: 2010

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 (22.05.2022) of the certificate of 93/42/EEC.

Winston Tsai

Signature: **Winston Tsai, Management Representative**

Date: Dec. 28, 2020