

rossmax	EC Declaration of Conformity	Doc No.	RD-4-002
		Version	I
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		Effective Date	2014/02/14

1. EC Declaration of Conformity

Manufacturer	: Rossmax Swiss GmbH
Address	Widnauerstrasse 1, CH-9435 Heerbrugg, Switzerland
Notified Body	: SGS Belgium NV
Address	: SGS House Noorderlaan 87 2030 Antwerp Belgium
EU Identification No.	: 1639
Certificate No.	: TW19/20056
Representative in Europe	: CMC Medical Devices& Drugs S.L.
Address	C/ Horacio Lengo No 18, CP 29006, Málaga, Spain
Product type	: Non-Invasive Blood Pressure Measuring Device with pulse arrhythmia detecting function (including Afib(Atrial Fibrillation), PC(Premature Contraction), TACH(Tachycardia) and BRAD (Bradycardia)
Type Designation	: AC1000f, X9
Conformity Assessment	: EU Council Directive 93/42/EEC amended by 2007/47/EC Annex II (excluding Section 4)
Classification	: Class IIa (According to EU Council Directive 93/42/EEC amended by 2007/47/EC, Annex IX, Rule 10)
Serial No.	: YY M 001 - 000001
	<div style="display: flex; align-items: center;"> <div style="border-left: 1px solid black; width: 100px; height: 100px; margin-right: 10px;"></div> <div> <p>Sequential number</p> <p>Lot sequential number</p> <p>Manufacturing month.</p> <p>Manufacturing year.</p> </div> </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 (22.05.2023) of the certificate of 93/42/EEC.

Winston Tsai

Signature: **Winston Tsai, Management Representative**

Date: May. 26, 2021