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) and Regulation (EU) 2023/607 amendment of Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices
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

Sequential number

Lot sequential number

Manufacturing month.

Manufacturing year.

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, 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 14971:2019, 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: Jun. 13, 2023