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 International Ltd.
Address		12F., No 189, Kang Chien Rd., Taipei 114, Taiwan
Notified Body	:	SGS Fimko Ltd.
Address	:	Särkiniementie 3, 00210 Helsinki, Finland
EU Identification No.	:	0598
Certificate No.	:	FI20/07007
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 Upper Arm Automatic Type
Type Designation	:	MA801f, CG155f
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 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, 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 International Ltd. 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.

Signature: **Winston Tsai, Management Representative**
Date: Apr. 27, 2020

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Manufacturer	:	Rossmax International Ltd.
Address		12F., No 189, Kang Chien Rd., Taipei 114, Taiwan
Notified Body	:	SGS Fimko Ltd.
Address	:	Särkiniementie 3, 00210 Helsinki, Finland
EU Identification No.	:	0598
Certificate No.	:	FI20/07007
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 Wrist Automatic Type
Type Designation	:	S150
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 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, 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

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1. EC Declaration of Conformity

Manufacturer	:	Rossmax International Ltd.
Address		12F., No 189, Kang Chien Rd., Taipei 114, Taiwan
Notified Body	:	SGS Fimko Ltd.
Address	:	Särkiniementie 3, 00210 Helsinki, Finland
EU Identification No.	:	0598
Certificate No.	:	FI20/07007
Representative in Europe	:	CMC Medical Devices& Drugs S.L.
Address		C/ Horacio Lengo No 18, CP 29006, Málaga, Spain
Product type	:	Infrared Ear Thermometer
Type Designation	:	RA600
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)
Lot No.	:	YY M XXX

YY → Manufacturing year.
M → Manufacturing month.
XXX → Lot sequential number

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, 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 14971:2012, 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

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