

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

## 1. EC Declaration of Conformity

<b>Manufacturer</b> Address	: Rossmax Swiss GmbH Widnauerstrasse 1, CH-9435 Heerbrugg, Switzerland
<b>Notified Body</b> Address EU Identification No.	: SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp Belgium 1639
Certificate No.	: TW19/20056
<b>Representative in Europe</b> Address	: CMC Medical Devices & Drugs S.L. C/ Horacio Lengo No 18, CP 29006, Málaga, Spain
<b>Product type</b>	: Non-Invasive Blood Pressure Measuring Device Wrist Automatic Type
<b>Type Designation</b>	: BK150, K150, S150, BC351(KS452), BI701, BQ705, BR705, BS705, X150
<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>Serial No.</b>	: <u>YY M 001 - 000001</u> <div style="margin-left: 40px;">             ↘ Sequential number              ↘ Lot sequential number              ↘ Manufacturing month.              ↘ Manufacturing year.           </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, 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, EN60601-1-11:2010

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 (31.12.2028) of the certificate of 93/42/EEC.

Yolanda Lin  
 Signature: Yolanda Lin, Management Representative  
 Date: Jun. 13, 2023