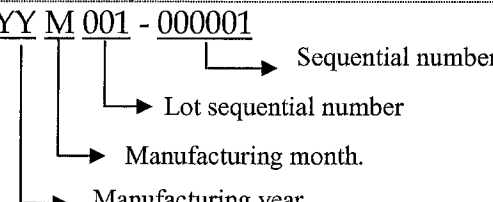


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| Doc No. | RD-4-002 |
| Version | I |
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| Effective Date | 2014/02/14 |

1. EC Declaration of Conformity

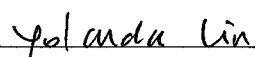
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|--|--|
| Manufacturer Address | : Rossmax Swiss GmbH Widnauerstrasse 1, CH-9435 Heerbrugg, Switzerland |
| Notified Body Address EU Identification No. | : SGS Belgium NV : SGS House Noorderlaan 87 2030 Antwerp Belgium : 1639 |
| Certificate No. | : TW19/20056 |
| Representative in Europe Address | : CMC Medical Devices & Drugs S.L. 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. | : <u>YY M 001 - 000001</u> <div style="margin-left: 40px;">  </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, EN 62304:2006/AC2008, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015

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.


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