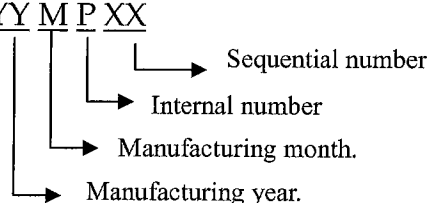


Doc No.	RD-4-002
Version	I
Page	1/1
Effective Date	2014/02/14

## 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>	: Nebulizer (including nebulizer pack, nebulizer bottle set) for respiratory therapy
<b>Type Designation</b>	: Nebulizer accessory pack (NB_AC_002_RM, NB_AC_002_AM, NB_AC_010_RM, NB_AC_010_AM, NB_AC_042_RM, NB_AC_019_RM)
<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 5-used with mouthpiece Rule2-used with mask
<b>Lot No.</b>	: <u>YY M P XX</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 ISO 10993-1:2009/ AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 13485:2016, EN ISO 14971:2012, EN 13544-1:2007+A1:2009

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