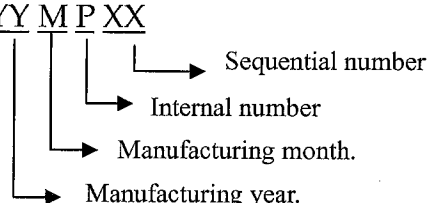


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Effective Date	2014/02/14

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	: Nebulizer (including nebulizer pack, nebulizer bottle set) for respiratory therapy
Type Designation	: adult mask(NB_AC_003_00,NB_AC_038_00), child mask (NB_AC_004_00, NB_AC_039_00), Reusable Aerosol Mask and L-Connector (NB_AC_012_00, NB_AC_013_00, NB_AC_014_00), air tube (NB_AC_005_00, NB_AC_033_00), air filters (NB_AC_006_00, NB_AC_007_00, NB_AC_032_00)
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 2)
Lot No.	: <u>YY M P XX</u>
	

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 10993-1:2009/ AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 13485:2016, EN ISO 14971:2012

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