



EC Declaration of Conformity

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

1. EC Declaration of Conformity

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	: Nebulizer (including nebulizer pack, nebulizer bottle set) for respiratory therapy
Type Designation	: NA100, NB500, NF100, NB80, NF80, NB60, NE100, NI60, NH60, NF60, NJ100, NK1000, NL100
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 11)
Lot No.	: <u>YY M 001</u> <ul style="list-style-type: none">→ 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, 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 13544-1:2007+A1:2009, EN ISO 10993-1:2009/ AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 13485:2016, EN ISO 14971:2019, EN 60601-1:2006/ A1 :2013, EN 60601-1-2:2015, 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.

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