EU Declaration of Conformity

Manufacturer	:	Rossmax Swiss GmbH
Address		Widnauerstrasse 1, CH-9435 Heerbrugg, Switzerland
SRN	:	CH-MF-000011245
Representative in Europe	:	CMC Medical Devices& Drugs S.L.
Address		C/ Horacio Lengo No 18, CP 29006, Málaga, Spain
Basic UDI-DI	:	4715139AerospacerN2
Product name	:	Spacer for Aerosol
Product code	:	AS175
Conformity Assessment	:	Regulation (EU) 2017/745 of the European Parliament and of the Council ANNEX II, ANNEX III, ANNEX IV
Classification	:	Class I (According to g Regulation (EU) 2017/745, Annex VIII, Rule 2- used with mask or Rule 5- used directly)
Lot No.	:	YY M P XX

YY → Manufacturing year.
M → Manufacturing month.
P → Internal number
XX → Sequential number

The above-mentioned devices are in full compliance with the relevant provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council, Annex I-General Safety and Performance Requirements and applied harmonized standards, national standards or other normative documents and, if applicable, common specification.

EN ISO 14971:2019, EN1041:2008, EN ISO15223-1:2021, EN ISO 13485:2016, EN ISO 10993-1:2009/ AC2010, EN ISO 10993-5:2009 EN ISO 10993-10:2013, EN 62366:2008

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.

Yolanda Lin

Signature: **Yolanda Lin, Management Representative**

Date: Feb. 20, 2023