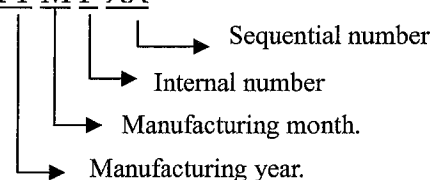


Doc No.	RD-4-136
Version	A
Page	1/1
Effective Date	2021/6/2

## EU Declaration of Conformity

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