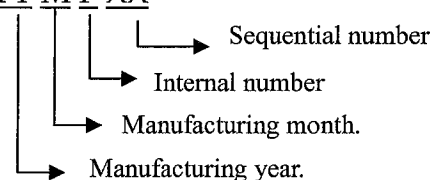


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EU Declaration of Conformity

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.	: <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