



TRUDELL MEDICAL
INTERNATIONAL

Declaration of Conformity

Product: **AeroChamber Plus* Flow-Vu*** anti-static VHC

Type: Valved Holding Chamber with Small Mask (REF 108507)
Valved Holding Chamber with Medium Mask (REF 108502)
Valved Holding Chamber with Adult Small Mask (REF 108508)
Valved Holding Chamber with Adult Large Mask (REF 108504)

Basic UDI-DI: 762860VHC1NL

Trudell Medical International hereby declares that the above-mentioned product complies with the applicable provisions of Annexes II & III of the European Medical Device Regulation 2017/745

This declaration of conformity is issued under the sole responsibility of Trudell Medical International.

Trudell Medical International SRN #: CA-MF-000009860

Device Class per MDR (EU) 2017/745: Class I per rule 2

Intended Purpose: This chamber is intended to be used by patients who are prescribed a metered dose inhaler or soft mist inhaler, to deliver the aerosol medication from the inhaler to your lungs.

The EU Authorized Representative is:

SRN #: NL-AR-000000116

Emergo Europe

Prinsessegracht 20

2514 AP The Hague

The Netherlands

Our quality system is registered to ISO 13485:2016.

Should you have any questions or concerns with regards to this document please feel free to direct them to my attention by phone at +1(519) 455-7060.

Sincerely,

Marianne Tanton
Director, Quality and Regulatory Affairs
Trudell Medical International
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London, Ontario, Canada N5V 5G4

Date: 07-Dec-2021

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