Trudell Medical International*

Declaration of Conformity

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

Type:
Valved Holding Chamber with Small Mask
Valved Holding Chamber with Medium Mask
Valved Holding Chamber with Adult Small Mask
Valved Holding Chamber with Adult Large Mask
Valved Holding Chamber with Youth Mouthpiece
Valved Holding Chamber with Mouthpiece

Trudell Medical International hereby declares that the above-mentioned product complies with the applicable provisions of **Annex VII of the European Medical Device Directive 93/42/EEC as amended by Council Directive 2007/47/EC** and its relevant transposition into all national laws of the Member States into which we place the devices.

Device Class per MDD 93/42/EEC: **Class I** per rule 2 (mask) and 5 (mouthpiece)

The EU Authorized Representative is:
Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

In addition, we declare that the above-mentioned device fulfills the applicable provision(s) of the following;

- Canadian Medical Device Regulation, (CMDR): May 1998
- US FDA 21 CFR Part 820, Quality System Regulation

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
725 Baransway Drive
London, Ontario, Canada N5V 5G4

Date: 04Jun2019