TRUDELL MEDICAL INTERNATIONAL

Declaration of Conformity

Product: ***AeroChamber Plus* Flow-Vu**** Anti-Static Valved Holding Chamber

Type: Valved Holding Chamber with Youth Mouthpiece (REF 108509)
Valved Holding Chamber with Mouthpiece (REF 108501)

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 5 (mouthpiece)

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

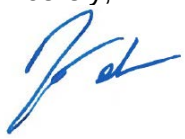
In addition, we declare that the above-mentioned device fulfills the applicable provision(s) of the following;

- 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
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London, Ontario, Canada N5V 5G4

Date: 31Mar2021