Trudell Medical International*

Declaration of Conformity

Product: ***AeroChamber2go**** anti-static Valved Holding Chamber (REF 123501)

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 5

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: 14May2021