



Trudell Medical International

Certificate of Compliance

This letter is to certify that Trudell Medical International assembles the following finished product using only inspected and approved material.

Product Line: AEROCHAMBER PLUS* FLOW-VU* Anti-Static VHC

Product Type: Valved Holding Chamber (VHC) - Mouthpiece
Valved Holding Chamber (VHC) – Small Mask
Valved Holding Chamber (VHC) – Medium Mask
Valved Holding Chamber (VHC) – Large Mask

These products are manufactured and packaged according to the requirements of the current approved manufacturing specifications. All batch documentation (Certificates of Compliance for components) is available upon request.

Declaration of Conformity

Trudell Medical International hereby declares that the above mentioned products comply 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**

In addition, we declare that the above mentioned devices fulfill the applicable provision(s) of the following;

- Canadian Medical Device Regulation, (CMDR): May 1998
- US FDA 21 CFR Part 820, Quality System Regulation (October 1996)

Our quality system is registered to **ISO 13485:2003** (certificate number CERT-0061872)

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 or by fax at +1(519) 455-9429.

Sincerely,

Darryl Fischer, CQM
Associate Director, Global Regulatory Affairs

Date: 25 Nov 2014