TRUDELL MEDICAL
INTERNATIONAL

Declaration of Conformity

Product: ***Aerobika**** Oscillating Positive Expiratory Pressure (OPEP) Device (REF 110501)

Basic UDI-DI: 762860OPEP1G4

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 5

Intended Purpose: The device is intended for use as a Positive Expiratory Pressure (PEP) device. The device may also be used simultaneously with nebulized aerosol drug delivery. The device is intended to be used by patients capable of generating exhalation flow of 10 L/min for 3–4 seconds.

The EU Authorized Representative is:
SRN #: NL-AR-000000116
Emergo Europe
Westervoortsedijk 60, 6827 AT Arnhem, 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
725 Baransway Drive, London, Ontario, Canada N5V 5G4

Date: 07-Feb-2023