

Declaration of Conformity



Precision Medical Inc.
300 Held DR.
Northampton, PA, USA, 18067



Emergo Europe
Prinsessegracht 20
2514 AP, The Hague
The Netherlands



Product: Air-Oxygen Blenders
Model: PM5200 / PM5300 Series

CE
2460

Classification: IIb

Classification Criteria: Clause 3.2 Rule 11 of Annex IX of MDD

We hereby declare that the distributed CE marked products, specified in the Annexed product list, conform to the product(s) covered by "EC Certificate – Full Quality Assurance" Certificate No. CE 2460, first issued DATE delivered by DNV GL Presafe AS, Notified Body Identification Number 2460, in accordance with Annex II, excluding Section 4 for Class IIb products as defined in the Council Directive 93/42/EEC of 14 June 1993 and as amended by Directive 2007/47/EC of 5 September 2007.

Notified Body:



DNV GL Presafe AS
Veritasveien 3
1363 Hovik
Norway
Phone: +47 67578800

Certification Registration No's: 10000374838 Date of Expiry: 27MAY2024

Devices already manufactured: SN traceability via Device History Records
Validity of DOC: Date of Issue to Date of Expiry

I, the undersigned, hereby declare under my sole responsibility the equipment specified above meets the essential requirement and conforms to the follow, as certified by DNV GL Presafe AS, Notified Body Identification Number 2460.

Manufacture Representative:

Brian Klotz

Signature: _____

Position:

Quality Manager

Date of Issue:

26 MARCH 2021