Declaration of Conformity

Precision Medical Inc.
300 Held Drive
Northampton Pa 18067 USA

EC REP

Emergo Europe (European Office)
Prinsessegracht 20
2514 AP, The Hague
The Netherlands
Phone: +31 (0) 70.345.8570
Fax: +31 (0) 70.346.7299

CE 0473

REF

Precision Medical Air\Oxygen Low Flow Blenders;
PM5300EN, PM5300MEN, PM5300NIST, PM5300NISTAP, PM5300NISTAPMR

Precision Medical Air\Oxygen High Flow Blenders;
PM5200EN, PM5200MEN, PM5200NIST, PM5200NISTAP

Precision Medical Helium Oxygen, $HeliO_2$, 70\30% Low Flow Blenders;
PM5470EN, PM5470NIST

Precision Medical Helium Oxygen, $HeliO_2$, 80\20% Low Flow Blenders;
PM5480EN, PM5480NIST,

Precision Medical Helium Oxygen, $HeliO_2$, 70\30% High Flow Blenders;
PM5570EN, PM5570NIST

Precision Medical Helium Oxygen, $HeliO_2$, 80\20% High Flow Blenders;
PM5580EN, PM5580NIST

Classification: IIb

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

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II, 3 of the Directive 93/42/EEC and Directive 2007/47/EC on medical devices.

We certify that the production quality system conforms to the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed above.

Applied Standards:

EN 1041:2008	EN ISO 14971:2012
ISO 11195:1995	EN ISO 15001:2011
EN ISO 13485:2012	ISO 15223-1:2012

Notified Body: Intertek AMTAC Certification Services Limited CE 0473

Address: Davy Avenue Knowlhill Milton Keynes MK5 8NL, UK

Certification Registration No's: 1126-02 CE Date of Expiry: 31 January 2018

Devices already manufactured: SN traceability via Device History Records
Validity of DOC: 04/August/2012 to Date of Expiry

Manufacture Representative: James Parker Signature: Digitally signed by James Parker Date: 2017.07.20 09:43:19 -04'00'

Position: Manager, Quality System/ISO Representative

Date of Issue: 28 June 2017