

Certificate of Approval

This is to certify that the Management System of:

Precision Medical Inc.

300 Held Drive, Northampton, PA, 18067, United States

MDSAP Facility Identifier: F003537

has been audited by LRQA and found to conform to the following audit criteria:

ISO 13485:2016

Australia:

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 – Full Quality Assurance Procedure

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 4 – Production Quality Assurance Procedure

Canada:

Medical Devices Regulations – Part 1- SOR 98/282

Japan:

MHLW Ministerial Ordinance 169, Article 4 to Article 68

PMD Act

United States:

21 CFR 803

21 CFR 806

21 CFR 807 – Subparts A to D

21 CFR 820

Approval number: MDSAP – 0078924

The scope of this approval is applicable to:

Design, Development, Manufacturing, Servicing and Distribution of Oxygen Concentrators, Compressors, Aspirators, Flowmeters, Oxygen Regulators, Vacuum Regulators, Oxygen Regulators, Medical Gas Blenders, Oxygen Monitors and associated fittings and couplers.

Cliff Muckleroy

Area Operations Manager Americas

Issued by: LRQA Limited

for and on behalf of: Lloyd's Register Quality Assurance, Inc.



LRQA Limited is an MDSAP authorised auditing organization.

To validate certificate authenticity visit: <http://www.lrqausa.com/help-and-support/Request-for-certificate-verification>

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