

# Certificate of Approval

This is to certify that the Management System of:

## Precision Medical Inc.

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

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

Medical Device Single Audit Program 2017

**ISO 13485:2016**

**Australia:**

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1– Full Quality Assurance System  
Schedule 3, Part 4 - Production Quality Assurance Procedures

**Canada:**

Medical Devices Regulations – Part 1- SOR 98/282

**Japan:**

MHLW Ministerial Ordinance 169, Article 4 to Article 68  
PMD Act (as applicable)

**United States:**

21 CFR 820

21 CFR 803

21 CFR 806

21 CFR 807 – Subparts A to D



David Derrick- Area Operations Manager UK & Ireland  
Issued By: Lloyd's Register Quality Assurance, Inc.

Current issue date: 19 December 2018

Expiry date: 18 December 2021

Certificate identity number: 10168855

Certificate Approval No: UQA00000657/A

Original approval(s):

MDSAP – 19 December 2018

Product Approval number: MDSAP – 0078924



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The scope of this approval is applicable to:

Design, Development, Manufacturing, Servicing and Distribution of Oxygen Concentrators, Compressors, Aspirators, Conserving Flowmeters, Oxygen Regulators, Vacuum Regulators, Oxygen Conserving Regulators, Medical Gas Blenders, Oxygen Monitors and Associated Fittings and Couplers.

