

## **CERTIFICATE**OF REGISTRATION

This is to certify that the management system of:

## **Precision Medical Inc.**

(FIN # F006238)

Main Site: 300 Held Drive

Northampton, PA, 18067, United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

## ISO 13485:2016

**Australia**: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

## The management system 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.

Organization was certified by another Certification Body before 7/25/2022

**Certificate Number:** 

0124829-02

**Initial Certification Date:** 

2018-12-19

**Certification Effective Date:** 

2023-01-23

**Certification Expiry Date:** 

2024-12-18



Calin Moldovean

President, Business Assurance

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