



CERTIFICATE OF REGISTRATION

Pergola S.r.L.

via Statale, no 11/13, 25011 Ponte San Marco di Calcinato - BS (Italy)
ITALY

D-U-N-S ID No. 630141950

UL Medical Regulatory Services of UL LLC®(UL) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

Design and manufacturing of valves for high pressure cylinders and regulators for oxygen therapy for home and hospital use, and for administration of O2 and N2O mixtures, heliox and medical air.



Authorized by



Check Certificate
Status: [here](#)

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
UL Life and Health Sciences
UL LLC

File Number	A28700	Cycle Start Date	April 19, 2019
Certificate Number	2398.190419	Effective Date	April 19, 2019
Initial Issue Date	April 19, 2019	Expiry Date	April 18, 2022

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC. Certificates may be verified by visiting the Online Certifications Directory on UL.com.



**UL Medical and Regulatory
Services UL, LLC is an MDSAP
Recognized Auditing
Organization**

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA



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Additional Regulatory Requirements

Australia:

- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil:

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

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
- 21 CFR 821 (where applicable)

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