Certificate of Registration

Certificate number
2398.250419

File number
A28700

Initial issue date
2019-04-19

Cycle start date
2025-04-19

Effective date
2025-04-19

Expiry date
2028-04-18

Cavagna Group S.p.A – Divisione Omeca

via Statale
no 11/13
25011 Ponte San Marco di Calcinato ITALY

Facility ID: F002689

UL LLC, UL Solutions medical and regulatory services issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016
EN ISO 13485:2016/A11:2021

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

Design and manufacture of high pressure cylinder valves, pressure regulators and their accessories for medical use.

Certificate with Addendum(s) totals 3 pages.

Authorized by:

Paul Daysh
Operations manager – Medical Regulatory

Check certificate status: here

This quality system registration is included in UL's Product iQ directory and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown. By issuance of this certificate, the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferrable and remains the property of UL Solutions.

UL LLC, UL Solutions medical regulatory services is an MDSAP Recognized Auditing Organization

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

Addendum 1

Site	Company Name	Location	Performing
1-1	Cavagna Group S.p.A – Divisione Omeca	via Statale, no 11/13 25011 Ponte San Marco di Calcinato ITALY Facility ID: **F002689**	All activities applicable to the QMS.

Additional Regulatory Requirements

Cavagna Group S.p.A – Divisione Omeca
via Statale
no 11/13
25011 Ponte San Marco di Calcinato ITALY

Facility ID: F002689

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

Brazil:
- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- 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)