CERTIFICATE OF REGISTRATION

Leventon S.A.U.

C/ Newton, 18-24
08635 Sant Esteve Sesrovires, Barcelona SPAIN

REPs Facility ID: F005408

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 manufacture of sterile IV flow regulators, elastomeric infusion pumps, cytostatic administration sets, infusion catheters, non-sterile respiratory exercisers and volumetric exercisers.

With additional locations listed on Addendum: 1

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Authorized by

Deborah Jennings-Conner

Deborah Jennings-Conner
Global Regulatory Director
UL Life and Health Sciences
UL LLC

Check Certificate Status: here

File Number	A17783	Cycle Start Date	April 29, 2021
Certificate Number	3354.210429	Effective Date	April 29, 2021
Initial Issue Date	April 29, 2021	Expiry Date	June 8, 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 REGISTERED FIRM

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

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

CERTIFICATE OF REGISTRATION

Leventon S.A.U.

C/ Newton, 18-24
08635 Sant Esteve Sesrovires, Barcelona SPAIN

REPs Facility ID: F005408

Addendum 1

2-1	**Leventon S.A.U.**
REPs Facility ID: **F005438**	**Ronda de Can Margarit 38**
	Sant Esteve Sesrovires (Barcelona) 08635 SPAIN

Performing: Manufacture and packaging of elastomeric infusion pumps.

File Number	A17783	Cycle Start Date	April 29, 2021
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REPs Facility ID: **F005408**

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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