

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Laboratoires Urgo**
42 Rue de Longvic
Chenôve
21300
France

Facility ID Number: F005422

Holds Certificate No: **MDSAP 746881**

Statement of Conformity: The company listed on this certificate has been audited and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - 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; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, manufacturing and distribution of dressings, bandages for compression, electro medical devices and software for management of wounds.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-04-29

Effective Date: 2022-04-29

Expiry Date: 2025-04-28



BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 746881**

Location

Laboratoires Urgo
42 Rue de Longvic
Chenôve
21300
France
Facility ID Number: F005422

Registered Activities

Design of dressings, bandages for compression, electro medical devices and software for management of wounds.

Laboratoires Urgo
Parc Excellence 2000
2 Avenue de Strasbourg
Chevigny St Sauveur
21800
France
Facility ID Number: F006154

Manufacturing and distribution of dressings, bandages for compression, electro medical devices and software for management of wounds.



Original Registration Date: 2022-04-29

Effective Date: 2022-04-29

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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

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A Member of the BSI Group of Companies.