

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Dompé farmaceutici Spa**
Via San Martino 12-12/a
Milan
20122
Italy

DUNS Number: 42-816-6094

Holds Certificate No: **MDSAP 707632**

Statement of Conformity: The company listed on this certificate has been audited to 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; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, development, manufacture and distribution of sterile and non-sterile ophthalmic drug administration devices.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-09-12

Effective Date: 2019-09-12

Expiry Date: 2022-09-11



BSI Group America Inc. is an MDSAP authorized auditing organization

Certificate No: **MDSAP 707632**

Location	Registered Activities
Dompé farmaceutici Spa Via San Martino 12-12/a Milan 20122 Italy DUNS Number: 42-816-6094	Product release, vigilance
Dompé farmaceutici Spa Via campo di Pile l'Aquila 67100 Italy DUNS Number: 43-547-7388	Design, Development, Purchasing, Manufacturing, Product Release, Device Marketing Authorization, Facility Registration.



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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.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.