By Royal Charter

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

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™

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.

Original Registration Date: 2019-09-12 Effective Date: 2019-09-12 Expiry Date: 2022-09-11