

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Gilero, LLC
4319 S Alston Ave
Durham
North Carolina
27713-2487
USA

Holds Certificate Number:

MD 579290

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, manufacture and packaging of medical devices for: Drug delivery such as ocular injections and drug application, IV infusion and injection delivery, drug storage and mixing for infusion and injection, disinfecting and cleaning such as swabs, debriders and disinfection caps, and non-active devices such as those for bone collection, vacuum suction and tissue collection.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2012-03-12

Latest Revision Date: 2024-03-06

Effective Date: 2024-03-12

Expiry Date: 2027-03-11



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Certificate No: **MD 579290**

Location	Registered Activities
Gilero, LLC 158 Credle Street Pittsboro North Carolina 27312 USA	Manufacture and packaging of medical devices for: Drug delivery such as ocular injections and drug application, IV infusion and injection delivery, drug storage and mixing for infusion and injection, disinfecting and cleaning such as swabs, debridors and disinfection caps, and non-active devices such as those for bone collection, vacuum suction and tissue collection.
Gilero, LLC - Tijuana Avenida Paseo de la Reforma 8950-E1 Colonia Rubio Tijuana Baja California Mexico	Manufacture and packaging of medical devices for drug delivery, IV infusion and injection delivery, drug storage and mixing for infusion and injection.
Gilero, LLC 4319 S Alston Ave Durham North Carolina 27713-2487 USA	Design and development of medical devices for: Drug delivery such as ocular injections and drug application, IV infusion and injection delivery, drug storage and mixing for infusion and injection, disinfecting and cleaning such as swabs, debridors and disinfection caps, and non-active devices such as those for bone collection, vacuum suction and tissue collection.

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