

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

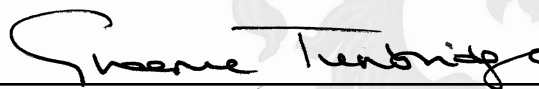
and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

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, and non-implantable active general medical devices for infusion and for inhalation.

Manufacture and packaging of medical devices for non-active soft tissue gastrointestinal implants.

Manufacture of injected molded plastic components for use in finished non implantable medical devices.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2012-03-12

Latest Revision Date: 2025-10-04

Effective Date: 2024-03-12

Expiry Date: 2027-03-11

Page: 1 of 2



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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000

BSI Assurance UK Limited, registered in England under number 7805321 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.

A Member of the BSI Group of Companies.

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 devices, drug storage and mixing for infusion and injection, devices for disinfecting and cleaning such as swabs, debriders, and cleaning cap, inactive instruments such as those for bone collection, vacuum suction and tissue collection, non-active soft tissue gastrointestinal implants, and non-implantable active general medical devices for infusion and for inhalation
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 devices, drug storage and mixing for infusion and injection, devices for disinfecting and cleaning such as swabs, debriders, and cleaning cap, and inactive instruments such as those for bone collection, vacuum suction and tissue collection, and non-implantable active general medical devices for infusion and for inhalation
Gilero, LLC - Greensboro 486 Gallimore Dairy Road Greensboro North Carolina 27409 USA	Manufacture of injected molded plastic components for use in finished non implantable medical devices.

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