

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Enable Injections
2863 E. Sharon Road
Cincinnati
Ohio
45241
USA

Facility ID Number: F008084

Holds Certificate No: **MDSAP 823758**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design and manufacture of a sterile, non-pyrogenic, single use, ambulatory bolus injector On Body Delivery Device and transfer system accessory for the subcutaneous delivery of liquid or reconstituted medicinal product into a patient.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2025-10-22

Effective Date: 2025-10-22

Expiry Date: 2028-10-21



BSI Group America Inc. is an MDSAP recognised auditing organization

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