



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Enable Injections 2863 E. Sharon Road Cincinnati Ohio 45241 USA

Holds Certificate No:

FM 635537

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

> 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 medicine medicinal product into a patient.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-12-19 Latest Revision Date: 2021-04-08





Effective Date: 2020-12-19 Expiry Date: 2023-12-18

Page: 1 of 1

...making excellence a habit."

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.