

# 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 Number:

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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-12-19

Latest Revision Date: 2023-09-25

Effective Date: 2023-12-19

Expiry Date: 2026-12-18

Page: 1 of 2



...making excellence a habit.™

Certificate No: FM 635537

Location	Registered Activities
Enable Injections 2863 E. Sharon Road Cincinnati Ohio 45241 USA	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.
Enable Injections, Inc. 301 Industrial Dr Franklin Ohio USA	The design and manufacture of a sterile, non-pyrogenic, singleuse, 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.



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Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

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