

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: 2020-10-28

Effective Date: 2020-12-19

Expiry Date: 2021-06-18

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