

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

embecta Medical II LLC
300 Kimball Dr.
Parsippany
New Jersey
07054
USA

Holds Certificate Number:

MD 812880

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

The design, development, manufacture, and distribution of drug delivery devices including syringes, pen needles, safety pen needles, and alcohol swabs for diabetes treatment and related conditions.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2025-02-25

Latest Revision Date: 2025-02-25

Effective Date: 2025-02-25

Expiry Date: 2027-08-16



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Certificate No: MD 812880

Location	Registered Activities
embecta Medical II LLC 300 Kimball Dr. Parsippany New Jersey 07054 USA	The design, development, and distribution of drug delivery devices including syringes, pen needles, safety pen needles, and alcohol swabs.
embecta Medical I LLC 1329 West Highway 6 Holdrege Nebraska 68949 USA	The manufacture and packaging of drug delivery devices including syringes and alcohol swabs.
embecta Penel Limited Pottery Road Dún Laoghaire, Co. Dublin A96 PC59 Ireland	The manufacture, packaging and sterilization of drug delivery pen needles and safety pen needles in accordance with ISO 11137-1:2006.
embecta Netherlands B.V c/o Regus Weerdestein 97 Amsterdam 1083 GG The Netherlands	Importation of medical devices and accessories for diabetes treatment and related conditions.

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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

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