Product Quality & Safety

embecta™

Product quality and safety

- embecta maintains a Quality Management System (QMS) with ISO 13485 certification *(detailed on next page, along with embecta Quality Policy).*
- The embecta Quality organization has procedures in place that direct the cross-functional assessment of product risks to patients through the design, manufacturing, and other lifecycle processes as appropriate for the product. Processes are in place throughout the manufacturing cycle to ensure adulterated product is not released. Post-market procedures exist to detect issues associated with released product, whether originating in the design or manufacturing process or via post-distribution alteration (e.g. counterfeit).
- Programs to assess and manage risks associated with potential inclusion of harmful chemicals have been developed
- Procedures are in place to properly qualify, audit, and monitor the performance of suppliers against quality standards established for these suppliers' materials. embecta's **Expectations for Suppliers (EFS)** establishes expectations for all suppliers with respect to governance, environmental stewardship, ethical practices and social responsibility.
- Regulatory, Quality and Sustainability organizations have procedures to assess regulatory requirements for our products in the markets where we have active distribution. Processes include surveillance of regulatory changes through a variety of channels, including industry group memberships. A standards management process exists to establish and maintain currency of standards for our products in the markets where we have active distribution.
- Quality processes and procedures are subject to an internal audit program, as well as audits (planned and unannounced) from regulatory agencies associated with the regions where we distribute our products.
- Associates involved in the design, manufacture, release, and post-market monitoring of product receive Quality training to ensure that they perform their functions in a manner that demonstrates compliance with all applicable regulations and standards.

Quality Policy and QMS Certification

Quality Policy

We will provide high quality products and work collaboratively with our customers to deliver on our mission of developing and providing solutions that make life better for people with diabetes. We are committed to maintaining and continually improving our Quality Management System to comply with all appropriate regulatory requirements.

Devdatt Kurdikar
President, Chief Executive Officer

Steve McDonnell
Vice President, Global Quality

embecta

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Embecta Corp.
300 Kimball Dr
Parsippany
New Jersey
07054
USA

Holds Certificate Number: FM 774044

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

The design, development, manufacturing, and distribution of diabetes drug delivery syringes, diabetes drug delivery pen needles, lancets, infusion sets, and accessories.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-08-11
Latest Revision Date: 2022-09-15

Effective Date: 2022-08-11
Expiry Date: 2024-08-16

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...making excellence a habit.

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

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