By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 816238 R000

Manufacturer: embecta Medical II LLC

Address:
300 Kimball Dr.
Parsippany
New Jersey
07054
USA

Single Registration Number: US-MF-000044225

EU Authorised Representative: embecta Penel Limited

Address:
Pottery Road
Dun Laoghaire Co.
Ireland

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2025-02-26**

Current Issue Date: **2025-02-26**

Starting Validity Date: **2025-02-26**

Expiry Date: **2030-02-25**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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EU Quality Management System Certificate

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Single-Use Syringes	Class IIa
Needles for Infusion and Sampling	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	30264395	Issued

First Issue Date: **2025-02-26**

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NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
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A Member of the BSI Group of Companies.

Manufacturer:	embecta Medical II LLC 300 Kimball Drive Parsippany, NJ 07054 USA
Manufacturer SRN:	US-MF-000044225
Authorised Representative:	embecta Penel Limited Pottery Road Dun Laoghaire Co. Dublin IRELAND
Authorised Representative SRN:	IE-AR-000040945
Product:	Micro-Fine Insulin Syringes Ultra-Fine Insulin Syringes
Basic UDI-DI:	0383017INLSYRNGJR8V (blister) 0383017INSLSYRNPBJR6K (polybagged)
Risk Class and Rule:	Class IIa, Rule 6
EMDN:	A02010601
GMDN:	38501
Intended Purpose	Insulin Syringes are sterile, single-use devices designed for subcutaneous administration of insulin.
Notified Body:	BSI CE 2797

We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Directives/ Regulation(s).

- Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices

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Conformity Assessment Route:

ANNEX IX Chapter I and III – Quality Management System	MDR 816238

Common Specifications (CS):

Number: <Version/Year>	Title:	Full or Partial Application: <Justification>
Common Specifications have not been issued for this product.		

Devices Covered by this DoC

SKU#	Device Name	Device Class	embecta Manufacturing Site
320801	Micro-Fine Insulin Syringes•U-40•12,7mm•29G•1mL•100ct	IIa	Holdrege, NE, USA
320829	Micro-Fine Insulin Syringes•U-100•8mm•30G•0,3mL•½ unit•100ct	IIa	Holdrege, NE, USA
320839	Micro-Fine Insulin Syringes•U-100•8mm•30G•0,3mL•½ unit•100ct	IIa	Holdrege, NE, USA
320840	Micro-Fine Insulin Syringes•U-100•8mm•30G•0,3mL•½ unit•30ct	IIa	Holdrege, NE, USA
320841	Micro-Fine Insulin Syringes•U-100•12,7mm•29G•1mL•100ct	IIa	Holdrege, NE, USA
320843	Micro-Fine Insulin Syringes•U-100•8mm•30G•0,5mL•100ct	IIa	Holdrege, NE, USA
320909	Micro-Fine Insulin Syringes•U-100•12,7mm•29G•1mL•100ct	IIa	Holdrege, NE, USA
320910	Micro-Fine Insulin Syringes•U-40•12,7mm•29G•1mL•100ct	IIa	Holdrege, NE, USA
320911	Micro-Fine Insulin Syringes•U-40•8mm•30G•1mL•100ct	IIa	Holdrege, NE, USA
320921	Micro-Fine Insulin Syringes•U-100•12,7mm•29G•0,5mL•100ct	IIa	Holdrege, NE, USA
320929	Micro-Fine Insulin Syringes•U-100•8mm•30G•1mL•100ct	IIa	Holdrege, NE, USA
320930	Micro-Fine Insulin Syringes•U-100•8mm•30G•0,5mL•100ct	IIa	Holdrege, NE, USA
320931	Micro-Fine Insulin Syringes•U-100•12,7mm•29G•1mL•100ct	IIa	Holdrege, NE, USA
320933	Micro-Fine Insulin Syringes•U-100•8mm•30G•0,5mL•100ct	IIa	Holdrege, NE, USA
320935	Micro-Fine Insulin Syringes•U-100•8mm•30G•1mL•100ct	IIa	Holdrege, NE, USA
324824	Micro-Fine Insulin Syringes•U-100•12,7mm•29G•0,5mL•100ct	IIa	Holdrege, NE, USA
324825	Micro-Fine Insulin Syringes•U-100•8mm•30G•0,5mL•100ct	IIa	Holdrege, NE, USA
324826	Micro-Fine Insulin Syringes•U-100•8mm•30G•0,3mL•½ unit•100ct	IIa	Holdrege, NE, USA
324827	Micro-Fine Insulin Syringes•U-100•12,7mm•29G•1mL•100ct	IIa	Holdrege, NE, USA
324876	Micro-Fine Insulin Syringes•U-40•8mm•30G•0,5mL•½ unit•100ct	IIa	Holdrege, NE, USA
324881	Micro-Fine Insulin Syringes•U-100•8mm•30G•0,5mL•30ct	IIa	Holdrege, NE, USA
324883	Micro-Fine Insulin Syringes•U-100•12,7mm•29G•1mL•30ct	IIa	Holdrege, NE, USA
324900	Ultra-Fine Insulin Syringes•U-100•6mm•31G•0,3mL•100ct	IIa	Holdrege, NE, USA
324901	Ultra-Fine Insulin Syringes•U-100•6mm•31G•0,5mL•100ct	IIa	Holdrege, NE, USA
324902	Ultra-Fine Insulin Syringes•U-40•6mm•31G•1mL•100ct	IIa	Holdrege, NE, USA
324903	Ultra-Fine Insulin Syringes•U-100•6mm•31G•1mL•100ct	IIa	Holdrege, NE, USA
324904	Micro-Fine Insulin Syringes•U-100•6mm•31G•0,5mL•100ct	IIa	Holdrege, NE, USA
324905	Micro-Fine Insulin Syringes•U-100•6mm•31G•1mL•100ct	IIa	Holdrege, NE, USA
324922	Micro-Fine Insulin Syringes•U-100•6mm•31G•0,3mL•½ unit•100ct	IIa	Holdrege, NE, USA
324923	Micro-Fine Insulin Syringes•U-100•6mm•31G•0,5mL•100ct	IIa	Holdrege, NE, USA
324924	Micro-Fine Insulin Syringes•U-100•6mm•31G•1mL•100ct	IIa	Holdrege, NE, USA
326103	Ultra-Fine Insulin Syringes•U-100•12,7mm•29G•0,3mL•100ct	IIa	Holdrege, NE, USA

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SKU#	Device Name	Device Class	embecta Manufacturing Site
326105	Ultra-Fine Insulin Syringes•U-100•12,7mm•29G•0,5mL•100ct	IIa	Holdrege, NE, USA
326110	Ultra-Fine Insulin Syringes•U-100•12,7mm•29G•1mL•100ct	IIa	Holdrege, NE, USA
326674	Ultra-Fine Insulin Syringes•U-100•6mm•31G•1mL•100ct•Blister	IIa	Holdrege, NE, USA
326675	Ultra-Fine Insulin Syringes•U-100•6mm•31G•0,5mL•100ct•Blister	IIa	Holdrege, NE, USA
326702	Ultra-Fine Insulin Syringes•U-100•8mm•30G•1mL•100ct•Blister	IIa	Holdrege, NE, USA
326719	Ultra-Fine Insulin Syringes•U-100•12,7mm•29G•1mL•100ct•Blister	IIa	Holdrege, NE, USA
326725	Ultra-Fine Insulin Syringes•U-100•8mm•30G•0,5mL•100ct•Blister	IIa	Holdrege, NE, USA
326769	Ultra-Fine Insulin Syringes•U-100•12,7mm•29G•0,5mL•100ct•Blister	IIa	Holdrege, NE, USA
328415	Ultra-Fine Insulin Syringes•U-100•12,7mm•27G•1mL•100ct•Blister	IIa	Holdrege, NE, USA
328457	Ultra-Fine Insulin Syringes•U-40•6mm•31G•1mL•100ct•Blister	IIa	Holdrege, NE, USA
328502	Ultra-Fine Insulin Syringes•U-40•8mm•31G•1mL•100ct	IIa	Holdrege, NE, USA
328820	Ultra-Fine Insulin Syringes•U-100•8mm•31G•1mL•100ct	IIa	Holdrege, NE, USA
328821	Ultra-Fine Insulin Syringes•U-100•8mm•31G•0,5mL•100ct	IIa	Holdrege, NE, USA
328822	Ultra-Fine Insulin Syringes•U-100•8mm•31G•0,3mL•100ct	IIa	Holdrege, NE, USA

Name: Jacques du Preez

Job Title: Director, Regulatory Affairs, EMEA

Signing for and on behalf of: embecta Medical II LLC

Place of Issue: Parsippany, NJ

Date of Issue:

Signature:

Signature: Jacques Du Preez
Electronically signed by: Jacques Du Preez
Reason: I approve this document.
Date: Aug 6, 2025 22:13:04 GMT+2

Email: jacques.du.preez@embecta.com

REVISION HISTORY:

Revision	Description Change:	Changes Made By:
1	Initial embecta SZ3 Pen Needle EU MDR Declaration of Conformity	Ruthanne Vendy
2	Addition of 3 Ultra-Fine U-40 31G 1 mL syringes (324902, 328457, 328502). Transferred to new revision of CP92037A. Updated revalidated B-UDI numbers with leading zero (0). Added USA to Manufacturer block. Replaced IE abbreviation with IRELAND.	Ruthanne Vendy

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TD01-MDR-DoC R2

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