

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) 0383017INLSYRNPBJR6K (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
<p>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).</p> <ul style="list-style-type: none"> Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices 	



EU Declaration of Conformity
TD01 – Insulin Syringes

Doc #:TD01-MDR-Doc
Ver/Rev: 02
Doc Type: ZQR

Conformity Assessment Route:

ANNEX IX Chapter I and III – Quality Management System	MDR 816238
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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	Ila	Holdrege, NE, USA
320829	Micro-Fine Insulin Syringes•U-100•8mm•30G•0,3mL•½ unit•100ct	Ila	Holdrege, NE, USA
320839	Micro-Fine Insulin Syringes•U-100•8mm•30G•0,3mL•½ unit•100ct	Ila	Holdrege, NE, USA
320840	Micro-Fine Insulin Syringes•U-100•8mm•30G•0,3mL•½ unit•30ct	Ila	Holdrege, NE, USA
320841	Micro-Fine Insulin Syringes•U-100•12,7mm•29G•1mL•100ct	Ila	Holdrege, NE, USA
320843	Micro-Fine Insulin Syringes•U-100•8mm•30G•0,5mL•100ct	Ila	Holdrege, NE, USA
320909	Micro-Fine Insulin Syringes•U-100•12,7mm•29G•1mL•100ct	Ila	Holdrege, NE, USA
320910	Micro-Fine Insulin Syringes•U-40•12,7mm•29G•1mL•100ct	Ila	Holdrege, NE, USA
320911	Micro-Fine Insulin Syringes•U-40•8mm•30G•1mL•100ct	Ila	Holdrege, NE, USA
320921	Micro-Fine Insulin Syringes•U-100•12,7mm•29G•0,5mL•100ct	Ila	Holdrege, NE, USA
320929	Micro-Fine Insulin Syringes•U-100•8mm•30G•1mL•100ct	Ila	Holdrege, NE, USA
320930	Micro-Fine Insulin Syringes•U-100•8mm•30G•0,5mL•100ct	Ila	Holdrege, NE, USA
320931	Micro-Fine Insulin Syringes•U-100•12,7mm•29G•1mL•100ct	Ila	Holdrege, NE, USA
320933	Micro-Fine Insulin Syringes•U-100•8mm•30G•0,5mL•100ct	Ila	Holdrege, NE, USA
320935	Micro-Fine Insulin Syringes•U-100•8mm•30G•1mL•100ct	Ila	Holdrege, NE, USA
324824	Micro-Fine Insulin Syringes•U-100•12,7mm•29G•0,5mL•100ct	Ila	Holdrege, NE, USA
324825	Micro-Fine Insulin Syringes•U-100•8mm•30G•0,5mL•100ct	Ila	Holdrege, NE, USA
324826	Micro-Fine Insulin Syringes•U-100•8mm•30G•0,3mL•½ unit•100ct	Ila	Holdrege, NE, USA
324827	Micro-Fine Insulin Syringes•U-100•12,7mm•29G•1mL•100ct	Ila	Holdrege, NE, USA
324876	Micro-Fine Insulin Syringes•U-40•8mm•30G•0,5mL•½ unit•100ct	Ila	Holdrege, NE, USA
324881	Micro-Fine Insulin Syringes•U-100•8mm•30G•0,5mL•30ct	Ila	Holdrege, NE, USA
324883	Micro-Fine Insulin Syringes•U-100•12,7mm•29G•1mL•30ct	Ila	Holdrege, NE, USA
324900	Ultra-Fine Insulin Syringes•U-100•6mm•31G•0,3mL•100ct	Ila	Holdrege, NE, USA
324901	Ultra-Fine Insulin Syringes•U-100•6mm•31G•0,5mL•100ct	Ila	Holdrege, NE, USA
324902	Ultra-Fine Insulin Syringes•U-40•6mm•31G•1mL•100ct	Ila	Holdrege, NE, USA
324903	Ultra-Fine Insulin Syringes•U-100•6mm•31G•1mL•100ct	Ila	Holdrege, NE, USA
324904	Micro-Fine Insulin Syringes•U-100•6mm•31G•0,5mL•100ct	Ila	Holdrege, NE, USA
324905	Micro-Fine Insulin Syringes•U-100•6mm•31G•1mL•100ct	Ila	Holdrege, NE, USA
324922	Micro-Fine Insulin Syringes•U-100•6mm•31G•0,3mL•½ unit•100ct	Ila	Holdrege, NE, USA
324923	Micro-Fine Insulin Syringes•U-100•6mm•31G•0,5mL•100ct	Ila	Holdrege, NE, USA
324924	Micro-Fine Insulin Syringes•U-100•6mm•31G•1mL•100ct	Ila	Holdrege, NE, USA
326103	Ultra-Fine Insulin Syringes•U-100•12,7mm•29G•0,3mL•100ct	Ila	Holdrege, NE, USA

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**EU Declaration of Conformity
TD01 – Insulin Syringes**

Doc #:TD01-MDR-Doc
Ver/Rev: 02
Doc Type: ZQR

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

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

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

Final Audit Report

2025-08-06

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