

<b>Manufacturer:</b>	embecta Medical II LLC 300 Kimball Drive Parsippany, NJ 07054 USA	
<b>Manufacturer SRN:</b>	US-MF-000044225	
<b>Authorised Representative:</b>	embecta Penel Limited Pottery Road Dun Laoghaire Co. Dublin IRELAND	
<b>Authorised Representative SRN:</b>	IE-AR-000040945	
<b>Product:</b>	Pen Needles: AutoShield Duo, Base-Fine, embecta, Micro-Fine, Micro-Fine PRO, Micro-Fine Ultra, Nano 2 <sup>nd</sup> Gen, Nano, SafeAssist, Ultra-Fine, Ultra-Fine PRO, Viva	
<b>Basic UDI-DI:</b>	Pen Needles:	0383017LGPNNLSCPVK
	AutoShield Duo Safety Pen Needles:	0383017SFPNASDNERYU
	SafeAssist Safety Pen Needles:	0383017SFPNNLSAH43J
<b>Risk Class and Rule:</b>	Class IIa, Rule 6	
<b>EMDN:</b>	A0101010201 (safety pen needles) A0101010202 (conventional pen needles)	
<b>GMDN:</b>	44127	
<b>Intended Purpose</b>	Pen Needles are sterile, single-use devices intended for use with pen injectors for subcutaneous injection of drugs by caregivers, laypersons, or health care professionals.	
<b>Notified Body:</b>	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"> <li>Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices</li> </ul>		

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**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
320120	Ultra-Fine Pen Needles•5mm•31G•3bevel•TW•6000ct	Ila	Dun Laoghaire, IRE
320123	Ultra-Fine Pen Needles•5mm•31G•3bevel•TW•50ct	Ila	Dun Laoghaire, IRE
320157	Nano Pen Needles•4mm•32G•3bevel•TW•6000ct	Ila	Dun Laoghaire, IRE
320179	Nano Pen Needles•4mm•32G•3bevel•TW•50ct	Ila	Dun Laoghaire, IRE
320190	Micro-Fine Pen Needles•8mm•30G•3bevel•RW•100ct	Ila	Dun Laoghaire, IRE
320207	Micro-Fine Ultra Pen Needles•12,7mm•29G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
320405	Ultra-Fine Pen Needles•4mm•32G•5bevel•UTW•100ct•Sample	Ila	Dun Laoghaire, IRE
320426	Viva Pen Needles•4mm•32G•3bevel•TW•100ct•Sample	Ila	Dun Laoghaire, IRE
320433	Micro-Fine Pen Needles•5mm•31G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
320434	Micro-Fine Pen Needles•4mm•32G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
320470	Micro-Fine Pen Needles•5mm•31G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE and Suzhou, China
320471	Micro-Fine Pen Needles•8mm•31G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE and Suzhou, China
320472	Micro-Fine Pen Needles•4mm•32G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE and Suzhou, China
320473	Micro-Fine Pen Needles•12,7mm•29G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
320477	Ultra-Fine Pen Needles•4mm•32G•5bevel•UTW•100ct	Ila	Dun Laoghaire, IRE and Suzhou, China
320497	Micro-Fine Pen Needles•4mm•32G•5bevel•TW•100ct	Ila	Dun Laoghaire, IRE and Suzhou, China
320498	Micro-Fine Pen Needles•5mm•31G•5bevel•TW•100ct	Ila	Dun Laoghaire, IRE and Suzhou, China
320499	Micro-Fine Pen Needles•8mm•31G•5bevel•TW•100ct	Ila	Dun Laoghaire, IRE and Suzhou, China
320500	Micro-Fine Ultra Pen Needles•4mm•32G•5bevel•UTW•100ct	Ila	Dun Laoghaire, IRE
320519	Micro-Fine Pen Needles•8mm•30G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
320520	Micro-Fine Pen Needles•4mm•32G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
320522	Ultra-Fine Pen Needles•5mm•31G•5bevel•UTW•105ct	Ila	Dun Laoghaire, IRE
320523	Ultra-Fine Pen Needles•6mm•31G•3bevel•TW•105ct	Ila	Dun Laoghaire, IRE
320524	Ultra-Fine Pen Needles•8mm•31G•5bevel•TW•105ct	Ila	Dun Laoghaire, IRE

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SKU#	Device Name	Device Class	embecta Manufacturing Site
320545	Ultra-Fine Pen Needles•5mm•31G•5bevel•UTW•140ct	Ila	Suzhou, China
320561	Ultra-Fine PRO Pen Needles•4mm•32G•5bevel•UTW•105ct	Ila	Dun Laoghaire, IRE
320562	Micro-Fine PRO Pen Needles•4mm•32G•5bevel•UTW•100ct	Ila	Dun Laoghaire, IRE
320564	Micro-Fine PRO Pen Needles•4mm•32G•5bevel•UTW•100ct•Sample	Ila	Dun Laoghaire, IRE
320566	Ultra-Fine PRO Pen Needles•4mm•32G•5bevel•UTW•100ct	Ila	Dun Laoghaire, IRE
320569	Ultra-Fine Pen Needles•5mm•31G•5bevel•UTW•100ct	Ila	Suzhou, China
320571	Ultra-Fine PRO Pen Needles•4mm•32G•5bevel•UTW•100ct•Sample	Ila	Dun Laoghaire, IRE
320575	Nano 2nd Gen Pen Needles•4mm•32G•5bevel•UTW•100ct	Ila	Dun Laoghaire, IRE
320585	Micro-Fine Ultra Pen Needles•4mm•32G•5bevel•UTW•100ct	Ila	Dun Laoghaire, IRE
320587	Micro-Fine Ultra Pen Needles•5mm•31G•5bevel•UTW•100ct	Ila	Dun Laoghaire, IRE
320590	Micro-Fine Pen Needles•5mm•31G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
320592	Micro-Fine Pen Needles•8mm•31G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
320594	Micro-Fine Pen Needles•5mm•31G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
320595	Micro-Fine Pen Needles•5mm•31G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
320649	Micro-Fine Ultra Pen Needles•4mm•32G•5bevel•UTW•100ct•Sample	Ila	Dun Laoghaire, IRE
320650	Micro-Fine Pen Needles•5mm•31G•5bevel•UTW•100ct•Sample	Ila	Dun Laoghaire, IRE
320651	Micro-Fine Pen Needles•8mm•31G•5bevel•TW•100ct•Sample	Ila	Dun Laoghaire, IRE
320697	Micro-Fine Pen Needles•6mm•32G•5bevel•TW•100ct	Ila	Dun Laoghaire, IRE
320698	Ultra-Fine Pen Needles•6mm•32G•5bevel•TW•105ct	Ila	Dun Laoghaire, IRE
320736	Micro-Fine Pen Needles•6mm•31G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
320737	Micro-Fine Pen Needles•6mm•31G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
320824	Base-Fine Pen Needles•4mm•32G•3bevel•TW•100ct	Ila	Suzhou, China
320825	Base-Fine Pen Needles•6mm•31G•3bevel•TW•100ct	Ila	Suzhou, China
320938	Base-Fine Pen Needles•5mm•31G•3bevel•TW•100ct	Ila	Suzhou, China
320940	Base-Fine Pen Needles•8mm•31G•3bevel•TW•100ct	Ila	Suzhou, China
320952	Micro-Fine Pen Needles•6mm•31G•3bevel•TW•100ct•Sample	Ila	Dun Laoghaire, IRE
320953	Micro-Fine Pen Needles•6mm•32G•5bevel•TW•100ct•Sample	Ila	Dun Laoghaire, IRE
320954	Micro-Fine Pen Needles•6mm•32G•5bevel•TW•90ct	Ila	Dun Laoghaire, IRE
321097	Micro-Fine Ultra Pen Needles•4mm•32G•5bevel•UTW•100ct	Ila	Dun Laoghaire, IRE
321098	Micro-Fine Pen Needles•5mm•31G•5bevel•UTW•100ct	Ila	Dun Laoghaire, IRE
321099	Micro-Fine Pen Needles•6mm•32G•5bevel•TW•100ct	Ila	Dun Laoghaire, IRE
321100	Micro-Fine Pen Needles•8mm•31G•5bevel•TW•100ct	Ila	Dun Laoghaire, IRE
321101	Viva Pen Needles•4mm•32G•3bevel•TW•90ct	Ila	Suzhou, China
321102	Viva Pen Needles•5mm•31G•3bevel•TW•90ct	Ila	Suzhou, China
321103	Viva Pen Needles•6mm•31G•3bevel•TW•90ct	Ila	Suzhou, China
321104	Viva Pen Needles•8mm•31G•3bevel•TW•90ct	Ila	Suzhou, China
321105	embecta Pen Needles•4mm•32G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
321106	embecta Pen Needles•5mm•31G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
321107	embecta Pen Needles•6mm•31G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
321108	embecta Pen Needles•8mm•30G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
321109	embecta Pen Needles•8mm•31G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
321110	embecta Pen Needles•12,7mm•29G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE


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EU Declaration of Conformity  
TD02 -Pen Needles

Doc #:TD02-MDR-DoC  
Ver/Rev: 02  
Doc Type: ZQR

SKU#	Device Name	Device Class	embecta Manufacturing Site
321115	Micro-Fine Ultra Pen Needles•4mm•32G•5bevel•UTW•100ct	Ila	Dun Laoghaire, IRE
321116	Micro-Fine Pen Needles•5mm•31G•5bevel•UTW•100ct	Ila	Dun Laoghaire, IRE
321117	Micro-Fine Pen Needles•6mm•31G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
321118	Micro-Fine Pen Needles•8mm•31G•5bevel•TW•100ct	Ila	Dun Laoghaire, IRE
321119	Micro-Fine Pen Needles•4mm•32G•5bevel•TW•90ct	Ila	Dun Laoghaire, IRE
321120	Micro-Fine Pen Needles•5mm•31G•5bevel•UTW•90ct	Ila	Dun Laoghaire, IRE
321121	Micro-Fine Pen Needles•6mm•31G•3bevel•TW•90ct	Ila	Dun Laoghaire, IRE
321122	Micro-Fine Pen Needles•8mm•31G•5bevel•TW•90ct	Ila	Dun Laoghaire, IRE
321123	Micro-Fine Pen Needles•12,7mm•29G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
321125	Ultra-Fine PRO Pen Needles•4mm•32G•5bevel•UTW•14ct	Ila	Dun Laoghaire, IRE
324841	Micro-Fine Pen Needles•12,7mm•29G•3bevel•TW•90ct	Ila	Dun Laoghaire, IRE
325107	Micro-Fine Ultra Pen Needles•5mm•31G•5bevel•UTW•100ct	Ila	Dun Laoghaire, IRE
325108	Micro-Fine Ultra Pen Needles•8mm•31G•5bevel•TW•100ct	Ila	Dun Laoghaire, IRE
325115	Micro-Fine Ultra Pen Needles•4mm•32G•5bevel•UTW•100ct•Sample	Ila	Dun Laoghaire, IRE
325118	Micro-Fine Ultra Pen Needles•12,7mm•29G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
329505	AutoShield Duo Pen Needles•5mm•30G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
329535	AutoShield Duo Pen Needles•5mm•30G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
329605	AutoShield Duo Pen Needles•5mm•30G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
329608	AutoShield Duo Pen Needles•8mm•30G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
329916	SafeAssist Pen Needles•5mm•30G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE
329917	SafeAssist Pen Needles•8mm•30G•3bevel•TW•100ct	Ila	Dun Laoghaire, IRE

**Name:** Heather Reed  
**Job Title:** Vice President, Global Regulatory Affairs  
**Signing for and on behalf of:** embecta Medical II LLC  
**Place of Issue:** Parsippany, NJ  
**Date of Issue:**  
**Signature:**   
**Email:** heather.reed@embecta.com

Electronically signed by: Heather Reed  
Reason: I approve this document.  
Date: Aug 21, 2025 15:26:29 EDT

**REVISION HISTORY:**

Revision	Description Change:	Changes Made By:
1	Initial embecta Pen Needles EU MDR Declaration of Conformity	Ruthanne Vendy
2	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. Added Micro to 325118.	Ruthanne Vendy

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# TD02-MDR-DoC PNs R2

Final Audit Report

2025-08-21

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