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:	Pen Needles: AutoShield Duo, Base-Fine, embecta, Micro-Fine, Micro-Fine PRO, Micro-Fine Ultra, Nano 2nd Gen, Nano, SafeAssist, Ultra-Fine, Ultra-Fine PRO, Viva
Basic UDI-DI:	Pen Needles: 0383017LGPNNDLSCPVK AutoShield Duo Safety Pen Needles: 0383017SFPNASDNERYU SafeAssist Safety Pen Needles: 0383017SFPNNLSAH43J
Risk Class and Rule:	Class IIa, Rule 6
EMDN:	A0101010201 (safety pen needles) A0101010202 (conventional pen needles)
GMDN:	44127
Intended Purpose	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.
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
320120	Ultra-Fine Pen Needles•5mm•31G•3bevel•TW•6000ct	IIa	Dun Laoghaire, Ireland
320123	Ultra-Fine Pen Needles•5mm•31G•3bevel•TW•50ct	IIa	Dun Laoghaire, Ireland
320157	Nano Pen Needles•4mm•32G•3bevel•TW•6000ct	IIa	Dun Laoghaire, Ireland
320179	Nano Pen Needles•4mm•32G•3bevel•TW•50ct	IIa	Dun Laoghaire, Ireland
320190	Micro-Fine Pen Needles•8mm•30G•3bevel•RW•100ct	IIa	Dun Laoghaire, Ireland
320207	Micro-Fine Ultra Pen Needles•12,7mm•29G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland
320405	Ultra-Fine Pen Needles•4mm•32G•5bevel•UTW•100ct•Sample	IIa	Dun Laoghaire, Ireland
320426	Viva Pen Needles•4mm•32G•3bevel•TW•100ct•Sample	IIa	Dun Laoghaire, Ireland
320433	Micro-Fine Pen Needles•5mm•31G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland
320434	Micro-Fine Pen Needles•4mm•32G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland
320470	Micro-Fine Pen Needles•5mm•31G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland and Suzhou, China
320471	Micro-Fine Pen Needles•8mm•31G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland and Suzhou, China
320472	Micro-Fine Pen Needles•4mm•32G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland and Suzhou, China
320473	Micro-Fine Pen Needles•12,7mm•29G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland
320477	Ultra-Fine Pen Needles•4mm•32G•5bevel•UTW•100ct	IIa	Dun Laoghaire, Ireland and Suzhou, China
320497	Micro-Fine Pen Needles•4mm•32G•5bevel•TW•100ct	IIa	Dun Laoghaire, Ireland and Suzhou, China
320498	Micro-Fine Pen Needles•5mm•31G•5bevel•TW•100ct	IIa	Dun Laoghaire, Ireland and Suzhou, China
320499	Micro-Fine Pen Needles•8mm•31G•5bevel•TW•100ct	IIa	Dun Laoghaire, Ireland and Suzhou, China
320500	Micro-Fine Ultra Pen Needles•4mm•32G•5bevel•UTW•100ct	IIa	Dun Laoghaire, Ireland
320519	Micro-Fine Pen Needles•8mm•30G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland
320520	Micro-Fine Pen Needles•4mm•32G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland
320522	Ultra-Fine Pen Needles•5mm•31G•5bevel•UTW•105ct	IIa	Dun Laoghaire, Ireland
320523	Ultra-Fine Pen Needles•6mm•31G•3bevel•TW•105ct	IIa	Dun Laoghaire, Ireland
320524	Ultra-Fine Pen Needles•8mm•31G•5bevel•TW•105ct	IIa	Dun Laoghaire, Ireland

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

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SKU#	Device Name	Device Class	embecta Manufacturing Site
321109	embecta Pen Needles•8mm•31G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland
321110	embecta Pen Needles•12,7mm•29G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland
321115	Micro-Fine Ultra Pen Needles•4mm•32G•5bevel•UTW•100ct	IIa	Dun Laoghaire, Ireland
321116	Micro-Fine Pen Needles•5mm•31G•5bevel•UTW•100ct	IIa	Dun Laoghaire, Ireland
321117	Micro-Fine Pen Needles•6mm•31G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland
321118	Micro-Fine Pen Needles•8mm•31G•5bevel•TW•100ct	IIa	Dun Laoghaire, Ireland
321119	Micro-Fine Pen Needles•4mm•32G•5bevel•TW•90ct	IIa	Dun Laoghaire, Ireland
321120	Micro-Fine Pen Needles•5mm•31G•5bevel•UTW•90ct	IIa	Dun Laoghaire, Ireland
321121	Micro-Fine Pen Needles•6mm•31G•3bevel•TW•90ct	IIa	Dun Laoghaire, Ireland
321122	Micro-Fine Pen Needles•8mm•31G•5bevel•TW•90ct	IIa	Dun Laoghaire, Ireland
321123	Micro-Fine Pen Needles•12,7mm•29G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland
321125	Ultra-Fine PRO Pen Needles•4mm•32G•5bevel•UTW•14ct	IIa	Dun Laoghaire, Ireland
324841	Micro-Fine Pen Needles•12,7mm•29G•3bevel•TW•90ct	IIa	Dun Laoghaire, Ireland
325107	Micro-Fine Ultra Pen Needles•5mm•31G•5bevel•UTW•100ct	IIa	Dun Laoghaire, Ireland
325108	Micro-Fine Ultra Pen Needles•8mm•31G•5bevel•TW•100ct	IIa	Dun Laoghaire, Ireland
325115	Micro-Fine Ultra Pen Needles•4mm•32G•5bevel•UTW•100ct•Sample	IIa	Dun Laoghaire, Ireland
325118	Micro-Fine Ultra Pen Needles•12,7mm•29G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland
329477	Ultra-Fine Pen Needles•4mm•32G•5bevel•UTW•5ct	IIa	Suzhou, China
329478	Micro-Fine Pen Needles•4mm•32G•5bevel•UTW•5ct	IIa	Suzhou, China
329479	Micro-Fine Pen Needles•4mm•32G•5bevel•UTW•5ct	IIa	Suzhou, China
329480	Micro-Fine Pen Needles•4mm•32G•5bevel•UTW•5ct	IIa	Suzhou, China
329505	AutoShield Duo Pen Needles•5mm•30G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland
329535	AutoShield Duo Pen Needles•5mm•30G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland
329605	AutoShield Duo Pen Needles•5mm•30G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland
329608	AutoShield Duo Pen Needles•8mm•30G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland
329916	SafeAssist Pen Needles•5mm•30G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland
329917	SafeAssist Pen Needles•8mm•30G•3bevel•TW•100ct	IIa	Dun Laoghaire, Ireland

Name: Jacques du Preez

Job Title: Senior Director, International Regulatory Affairs

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: Feb 13, 2026 08:59:26 GMT+1

Email: jacques.du.preez@embecta.com

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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
3	Added four 5-count 4mm•32G•5bevel•UTW pen needle SKU configurations: 329477, 329478, 329479, and 329480. Spelled out “Ireland” under Devices Covered by this DoC.	Ruthanne Vendy

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