NEEDLE CONCEPT - 1 Allée Pierre Georges Latécoère - 64200 Biarritz – France
SAS au capital de 713 212 Euros RCS Bayonne - SIRET : 508 230 331 00060 N° T.V.A. Intracom : FR 94508230331
Tél. : +33 (0)972 377 777 – contact@needleconcept.com

EU DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of Needle Concept, located at 1 Allée Pierre-Georges Latécoère 64200 Biarritz - France, SAS registered to RCS Bayonne, and identified in quality of manufacturer under SRN #FR-MF-000039283. We declare and guarantee that the products with CE mark covered by the below-mentioned list are class IIa devices according to Technical Documentation reference TF-INM current version. The device covered by this EU Declaration of Conformity complies with Regulation (EU) 2017/745 on medical devices.

Product code	*Product designation*	*UDI-DI code (secondary packaging)*	*UDI-DI code (tertiary packaging)*
INM25G25	HYPODERMIC NEEDLE – 25G Ø0.50 x 25mm	03760264551256	03760264551249
INM27G04	HYPODERMIC NEEDLE – 27G Ø0.40 x 4mm	03760264550556	03760264551010
INM27G06	HYPODERMIC NEEDLE – 27G Ø0.40 x 6mm	03760264550549	03760264551003
INM27G08	HYPODERMIC NEEDLE – 27G Ø0.40 x 8mm	03760264550532	03760264550990
INM27G12	HYPODERMIC NEEDLE – 27G Ø0.40 x 12mm	03760264550525	03760264550983
INM27G25	HYPODERMIC NEEDLE – 27G Ø0.40 x 25mm	03760264550518	03760264550976
INM30G04	HYPODERMIC NEEDLE – 30G Ø0.30 x 4mm	03760264550501	03760264550969
INM30G06	HYPODERMIC NEEDLE – 30G Ø0.30 x 6mm	03760264550495	03760264550952
INM30G08	HYPODERMIC NEEDLE – 30G Ø0.30 x 8mm	03760264550488	03760264550945
INM30G12	HYPODERMIC NEEDLE – 30G Ø0.30 x 12mm	03760264550471	03760264550938
INM30G25	HYPODERMIC NEEDLE – 30G Ø0.30 x 25mm	03760264550464	03760264550921
INM31G04	HYPODERMIC NEEDLE – 31G Ø0.25 x 4mm	03760264550457	03760264550914
INM31G06	HYPODERMIC NEEDLE – 31G Ø0.25 x 6mm	03760264551164	03760264551171
INM31G08	HYPODERMIC NEEDLE – 31G Ø0.25 x 8mm	03760264550440	03760264550907
INM31G12	HYPODERMIC NEEDLE – 31G Ø0.25 x 12mm	03760264550433	03760264550891
INM32G04	HYPODERMIC NEEDLE – 32G Ø0.23 x 4mm	03760264550426	03760264550884
INM32G06	HYPODERMIC NEEDLE – 32G Ø0.23 x 6mm	03760264551188	03760264551195
INM32G08	HYPODERMIC NEEDLE – 32G Ø0.23 x 8mm	03760264550419	03760264550877
INM32G12	HYPODERMIC NEEDLE – 32G Ø0.23 x 12mm	03760264550402	03760264550860
INM33G04	HYPODERMIC NEEDLE – 33G Ø0.20 x 4mm	03760264550396	03760264550853
INM33G06	HYPODERMIC NEEDLE – 33G Ø0.20 x 6mm	03760264551201	03760264551218
INM33G08	HYPODERMIC NEEDLE – 33G Ø0.20 x 8mm	03760264550389	03760264550846

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INM33G12	HYPODERMIC NEEDLE – 33G Ø0.20 x 12mm	03760264550372	03760264550839
INM34G04	HYPODERMIC NEEDLE – 34G Ø0.18 x 4mm	03760264550365	03760264550822
INM34G06	HYPODERMIC NEEDLE – 34G Ø0.18 x 6mm	03760264551225	03760264551232
INM34G08	HYPODERMIC NEEDLE – 34G Ø0.18 x 8mm	03760264550358	03760264550815
INM34G12	HYPODERMIC NEEDLE – 34G Ø0.18 x 12mm	03760264550341	03760264550808

EMDN code	A0101010102
GMDN code	59230
Basic UDI-DI	0376026455001TK
Classification according to Annex VIII – Regulation (EU) 2017/745	IIa, Rule 6
Conformity assessment procedure performed	Annex IX Chapters I and III with assessment of Technical Documentation according to Annex IX section 4.
Brand Name	HYPODERMIC NEEDLE
Intended Use	The HYPODERMIC NEEDLE is indicated to inject fluids into parts of the body below the surface of the skin.
Product Picture	

This declaration is based on UE certificate number 40360 rev. 0, delivered by GMED (CE #0459), located at 1 rue Gaston Boisier, 75015 Paris – France.

Issued on: **December 09, 2025**, at **Biarritz**.

Alexandre BAREILLE
General Manager