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-INC 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)*
INC14G90	MAGIC NEEDLE – 14G Ø2.10 x 90mm + 14G Ø2.10 x 12mm	03760264550693	03760264551157
INC16G70	MAGIC NEEDLE – 16G Ø1.60 x 70mm + 15G Ø1.80 x 12mm	03760264550686	03760264551140
INC16G90	MAGIC NEEDLE – 16G Ø1.60 x 90mm + 15G Ø1.80 x 12mm	03760264550679	03760264551133
INC18G70	MAGIC NEEDLE – 18G Ø1.20 x 70mm + 17G Ø1.40 x 12mm	03760264550662	03760264551126
INC18G90	MAGIC NEEDLE – 18G Ø1.20 x 90mm + 17G Ø1.40 x 12mm	03760264550655	03760264551119
INC20G70	MAGIC NEEDLE – 20G Ø0.90 x 70mm + 19G Ø1.10 x 12mm	03760264550648	03760264551102
INC20G90	MAGIC NEEDLE – 20G Ø0.90 x 90mm + 19G Ø1.10 x 12mm	03760264551263	03760264551270
INC22G57	MAGIC NEEDLE – 22G Ø0.70 x 57mm + 21G Ø0.80x 12mm	03760264550631	03760264551096
INC22G70	MAGIC NEEDLE – 22G Ø0.70 x 70mm + 21G Ø0.80x 12mm	03760264550624	03760264551089
INC22G90	MAGIC NEEDLE – 22G Ø0.70 x 90mm + 21G Ø0.80x 12mm	03760264550617	03760264551072
INC25G40	MAGIC NEEDLE – 25G Ø0.50 x 40mm + 23G Ø0.60 x 12mm	03760264550600	03760264551065
INC25G50	MAGIC NEEDLE – 25G Ø0.50 x 50mm + 23G Ø0.60 x 12mm	03760264550594	03760264551058
INC25G60	MAGIC NEEDLE – 25G Ø0.50 x 60mm + 23G Ø0.60 x 12mm	03760264550587	03760264551041
INC27G37	MAGIC NEEDLE – 27G Ø0.40 x 37mm + 26G Ø0.45 x 12mm	03760264550570	03760264551034
INC30G27	MAGIC NEEDLE – 30G Ø0.30 x 27mm + 27G Ø0.40 x 12mm	03760264550563	03760264551027

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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	MAGIC NEEDLE
Intended Use	The MAGIC NEEDLE are indicate 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