

Novo Nordisk A/S
NovoFine®
EU-Declaration of Conformity
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Final
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Novo Nordisk

EU – Declaration of Conformity

NovoFine®

EU - Declaration of Conformity

We, **The manufacturer**

Novo Nordisk A/S
Novo Allé
2880 Bagsværd
Denmark

SRN Code: DK-MF-000002222

hereby declare that the EU Declaration of Conformity is issued under our sole responsibility and that the following products are in conformity with the provisions of the European Union legislation:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR)

Product Name	Variant	Classification in accordance with Annex VIII	Basic UDI-DI	EMDN code	GMDN code
NovoFine®	30G 8 mm (0.3 x 8 mm)	Class IIa (Rule 6)	5712249000000400WV	A01010102	44127
NovoFine®	31G 6 mm (0.25 x 6 mm)	Class IIa (Rule 6)	5712249000000400WV	A01010102	44127
NovoFine®	32G 6 mm (0.23/0.25 x 6 mm)	Class IIa (Rule 6)	5712249000000400WV	A01010102	44127
NovoFine®	32G 4 mm (0.23/0.25 x 4 mm)	Class IIa (Rule 6)	5712249000000400WV	A01010102	44127

Intended purpose: *NovoFine® needles are intended for subcutaneous administration of fluids, such as solutions, suspensions, emulsions, from the cartridge of a compatible pen-injector.*

The devices have been subject to the conformity procedures laid down in Annex IX of the European Union Regulation (EU) 2017/745 under the supervision of TÜV SÜD Product Service GmbH (Certificate No. G10 011779 0507), carrying the Notified Body Identification Number 0123.

Location: Hjørring

On: 14 September 2022

By:


Peter M. Jensen, Director of Quality