# EU – Declaration of Conformity

# NovoFine® Autocover® 30G 8 mm

# 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 product is 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® Autocover® | 30G 8 mm (0.3 × 8 mm) | Class IIa (Rule 6) | 57122490000000500WZ | A01010102 | 44127 |

Intended purpose:

*NovoFine® Autocover® is intended for subcutaneous administration of fluids, such as solutions, suspensions, emulsions, from the cartridge of a compatible pen injector.*

The device has 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:_2022-06-02 By: Peter M. Jensen

Peter M. Jensen, Director of Quality