EC-Declaration of Conformity

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NovoFine®

30G 8 mm

31G 6 mm

32G 6 mm

32G 4 mm

Uma Prathyusha Gupta N
RA Device Established Products

EC - Declaration of Conformity

We, **Legal Manufacturer/ Market Authorization Holder**

Novo Nordisk A/S
Novo Allé
2880 Bagsværd
Denmark

Being the manufacturer/distributor within the European Economic Area, declare that this Declaration of Conformity is issued under our sole responsibility and covers the following product(s):

Product Name	**Item number** (*4 or 5-number*)	**Classification**	**GMDN Code**
NovoFine® 30G 8 mm	5-4325-21 5-4327-16	Class IIa	44127
NovoFine® 31G 6 mm	5-4356-16 5-4356-17	Class IIa	44127
NovoFine® 32G 6 mm	5-4314-18 5-4314-17	Class IIa	44127
NovoFine® 32G 4 mm	5-4401-11	Class IIa	44127

manufactured in the below mentioned production facilities:

Nipro Medical Industries Ltd., 2-19-64, Matsubara, Tatebayashi-shi, Gunma, 374-8518, Japan
Nipro (Thailand) Corporation Ltd., 10/2 Moo 8, Bangnomko, Sena, Phra Nakhon Si Ayutthaya, 13110, Thailand
Needle Manufacturing & Sourcing, Stenager Allé, 9800 Hjorring, Denmark

declare that the above is in conformity with the provisions of the Council Directive

European Council Medical Device Directive 93/42/EEC, of 14 June 1993, inclusive amendment 2007/47/EC of 5 September 2007.

The above devices are CE-marked and classified as IIa according to Annex IX, Classification Criteria, rule 6.

The devices have been subject to the conformity procedure laid down in Annex II under the supervision of TÜV SÜD Product Service GmbH, a Notified Body authorized by the German Competent Authority, and carrying the Notified Body number 0123.

Notified Body Address: TÜV SÜD PRODUCT SERVICE GMBH
PS-NAM1-MUC
Ridlerstr. 65
80339 Munchen
Germany

The following standards have been observed:

EN ISO 13485:2016/AC:2018	Medical devices - Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 11608-2:2012	Needle-based injection systems for medical use – Requirements and test methods – Part 2: Needles
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects – good clinical practice
EN 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices
ISO 11607-1: 2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging
ISO 11607-2:2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11135:2014/A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices – Amendment 1: Revision of Annex E, Single batch release (ISO 11135:2014/Amd 1:2018)
EN ISO 11737-1:2006 + AC:2009 (NMS)	Sterilization of medical devices – Microbiological Methods-Part 1: Determination of a population of microorganisms on products
EN ISO 11737-1:2018 (NMI)	Sterilization of medical devices – Microbiological Methods-Part 1: Determination of a population of microorganisms on products

EN ISO 11737-2: 2009 (NTC)	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 11737-2:2019 (NMI)	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration
EN ISO 14644-2:2015	Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

Location: Hjørring On: 2020.11.25 By: Peter M Jensen
Name & function of person signing
Director of Quality.