EC-Declaration of Conformity

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NovoPen Echo®

Sathya S
GRA Established Products CMC & Devices 1

Digitally signed by Chirtoacă Iurie
Date: 2022.02.03 18:30:14 EET
Reason: MoldSign Signature
Location: Moldova

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	Classification	GMDN Code
NovoPen Echo®	IIb	45771

manufactured in the below mentioned production facilities:

Novo Nordisk (China) Pharmaceutical Co., Ltd., Tianjin Plant, No. 99, Nanhai Road, TEDA 300457 Tianjin, P.R. China

are 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 device is CE-marked and classified as IIb according to Annex IX, Classification Criteria, rule 11.

The device has been subjected 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.

The following standards have been observed:

EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for regulatory purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 14155:2011	Clinical Investigation of Medical Devices for Human subjects – Good Clinical practices
ISO 10993-1:2018	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
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 Labels and Information to be Supplied – Part 1: General Requirements
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN 62304:2006+AC 2015	Medical device software - Software life-cycle processes

Location: Tianjin On: 2019.07.12 By: on behalf of NALU

Niels Laurbjerg Nielsen
Corporate Vice President