



## Certificate

No. Q5 011779 0503 Rev. 01

Applied Standard(s):

ISO 13485:2016

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -

Requirements for regulatory purposes

Facility(ies):

Novo Nordisk A/S

Novo Allé, 2880 Bagsvaerd, DENMARK

See Scope of Certificate.

Novo Nordisk (China) Pharmaceuticals Co., Ltd.

No. 99 Nanhai Road, TEDA, 300457 Tianjin, PEOPLE'S

REPUBLIC OF CHINA

Manufacture and packaging of drug delivery systems and peninjectors.

**Novo Nordisk A/S** 

Brennum Park 1, 3400 Hilleroed, DENMARK

Design and development of drug delivery systems, pen-injectors, self-injection aids, add-on connectivity devices, administration sets, needle guards, sterile single use hypodermic needles and pen needles. Manufacture of drug delivery systems and selfinjection aids.

Novo Nordisk A/S

Stenager Allé 4, 9800 Hjoerring, DENMARK

Manufacture of needle guards, sterile single use hypodermic needles and pen needles.

Novo Nordisk A/S

Hallas Allé 1, 4400 Kalundborg, DENMARK

Manufacture and packaging of Administration Sets (Procedure Pack).

**Parameters** 

.1.







## Certificate

No. Q5 011779 0503 Rev. 01

Novo Nordisk A/S **Holder of Certificate:** 

Novo Allé 2880 Bagsvaerd DENMAŘK

**Certification Mark:** 



Scope of Certificate: Design, development and manufacture of drug

> delivery systems, pen-injectors, self-injection aids, add-on connectivity devices, administration sets, needle guards and sterile single use hypodermic

needles and pen needles.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 011779 0503 Rev. 01

Report No.: 713297084

Valid from: 2023-11-10 Valid until: 2026-11-09

Date, 2023-11-06

Head of Certification/Notified Body

™Ѷ