



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: Scandinavian Health Ltd.
No. 136, Kuo Sheng 2nd Street
Taoyuan Dist.
Taoyuan City
330
Taiwan

Holds Certificate No: **MD 516137**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development and manufacture of drug delivery systems.
The contract manufacturing of drug delivery systems.
The design, development and manufacture of sterile single lumen needles.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2007-04-14

Latest Revision Date: 2018-12-03

Effective Date: 2019-04-13

Expiry Date: 2022-04-12

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +886 (02)2656-0333.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: **MD 516137**

Location	Registered Activities
Scandinavian Health Ltd. No. 136, Kuo Sheng 2nd Street Taoyuan Dist. Taoyuan City 330 Taiwan	The design, development and manufacture of drug delivery systems. The contract manufacturing of drug delivery systems. The design and development of sterile single lumen needles.
Scandinavian Health Ltd. No. 352-3, Sec 2, Nankan Rd. Luzhu Dist. Taoyuan City 338 Taiwan	The manufacture of drug delivery systems. The contract manufacturing of drug delivery systems.
Scandinavian Health Ltd. No. 6, 8, 10, Lane 421 Sec. 2, Nankan Rd. Luzhu Dist. Taoyuan City 338 Taiwan	The manufacture of drug delivery systems. The contract manufacturing of drug delivery systems.
Scandinavian Health Ltd. No. 1, Lane 421 Sec. 2, Nankan Rd. Luzhu Dist. Taoyuan City 338 Taiwan	The manufacture of drug delivery systems. The contract manufacturing of drug delivery systems.
SHL Group AB Floor 11 Augustendalsvägen 7 SE-131 28 Nacka Strand Sweden	The design and development of drug delivery systems.
Scandinavian Health Ltd. No. 352-2, Sec. 2, Nankan Rd. Luzhu Dist. Taoyuan City 338 Taiwan	The manufacture of drug delivery systems. The contract manufacturing of drug delivery systems.

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Location	Registered Activities
Scandinavian Health Ltd. No. 313, No. 313-1, Sec. 2, Nanshan Rd. Luzhu Dist. Taoyuan City 338 Taiwan	The manufacture of drug delivery systems. The contract manufacturing of drug delivery systems. The manufacture of sterile single lumen needles.
Scandinavian Health Ltd. No. 2 Lane 43, Shingbang Rd. Taoyuan Dist. Taoyuan City 330 Taiwan	The warehousing of drug delivery systems.
Scandinavian Health Ltd. No. 53, Lane. 17, Yuhe St. Taoyuan Dist. Taoyuan City 330 Taiwan	The manufacture of drug delivery systems. The contract manufacturing of drug delivery systems.

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