

# Certificate of Registration

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

This is to certify that:

Scandinavian Health Ltd.  
No. 36 Liufu Rd.  
Luzhu Dist.  
Taoyuan City  
338  
Taiwan

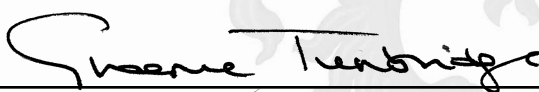
Holds Certificate Number:

MD 731144

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 and development of sterile and non-sterile drug delivery systems and sterile single lumen needles.  
The manufacture of non-sterile drug delivery systems and sterile single lumen needles.  
The contract manufacture of non-sterile drug delivery systems.

For and on behalf of BSI:

  
Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-06-04

Latest Revision Date: 2025-02-26

Effective Date: 2025-04-13

Expiry Date: 2028-04-12

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...making excellence a habit.™

Certificate No: MD 731144

Location	Registered Activities
Scandinavian Health Ltd. No. 136, Kuo Sheng 2nd Street Taoyuan Dist. Taoyuan City 330 Taiwan	The design and development of sterile and non-sterile drug delivery systems and sterile single lumen needles. The manufacture of non-sterile drug delivery systems. The contract manufacture of non-sterile 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 non-sterile drug delivery systems. The contract manufacture of non-sterile drug delivery systems.
Scandinavian Health Ltd. No. 1, Lane 421 Sec. 2, Nankan Rd. Luzhu Dist. Taoyuan City 338 Taiwan	The manufacture of non-sterile drug delivery systems. The contract manufacture of non-sterile drug delivery systems.
Scandinavian Health Ltd. No. 313, No. 313-1, Sec. 2, Nanshan Rd. Luzhu Dist. Taoyuan City 338 Taiwan	The manufacture of non-sterile drug delivery systems and sterile single lumen needles. The contract manufacture of non-sterile drug delivery systems.
Scandinavian Health Ltd. No. 2 Lane 43, Shingbang Rd. Taoyuan Dist. Taoyuan City 330 Taiwan	The warehousing of non-sterile drug delivery systems.
Scandinavian Health Ltd. No. 53, Lane 17, Yuhe St. Taoyuan Dist. Taoyuan City 330 Taiwan	The manufacture of non-sterile drug delivery systems. The contract manufacture of non-sterile drug delivery systems.

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Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Information and Contact:

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780

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