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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Scandinavian Health Ltd

Main site: No.36, Liufu Rd., Luzhu Dist., Taoyuan City 338, Taiwan

Additional sites according to appendix page 1-2

has been registered by Intertek as conforming to the requirements of

EN ISO 13485:2016 / ISO 13485:2016

The management system is applicable to:

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.

Certificate Number:
0221688
Revision:
01

Initial Certification Date:
11 August 2025

Date of Certification Decision:
28 August 2025

Certificate Valid Date:
28 August 2025

Certificate Expiry Date:
12 April 2028

SWEDAC ACKREDITERING
Ackred. nr. 10426
Certifiering av ledningssystem
ISO/IEC 17021-1

EN ISO 13485:2016 CERTIFICATION ™
Intertek

Brian Mather
Certification Authority, Intertek Medical Notified Body AB

Intertek Medical Notified Body AB
P.O. Box 1103, SE-164 22 Kista, Sweden

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The certificate remains the property of Intertek, to whom it must be returned upon request.

APPENDIX

This appendix identifies the locations by the management system of

Scandinavian Health Ltd

This appendix is linked to certificate #0221688-01 and cannot be shown nor reproduced without it.

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 2, Lane 43, Shingbang Rd., Taoyuan Dist., Taoyuan City, 330, Taiwan	The warehousing 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. 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.

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APPENDIX

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. 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

Certificate Number:	0221688-01
Initial Certification Date:	11 August 2005
Certificate Issue Date:	28 August 2025
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