10 March 2023 6 March 2026 10508472

Original approval(s): ISO 13485 - 7 June 2018

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Certificate of Approval

This is to certify that the Management System of:

Etteplan Sweden AB

Sperlingsgatan 5, 30248 Halmstad, Sweden

has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 - 00002046

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

LRQA Group Limited, its affiliates and subsidiaries and their respective officers, employees or agents are, individually and collectively, referred to in this clause as 'LRQA'.

The scope of this approval is applicable to:

Design service company, developing software, electronics, and mechanics for medical device manufacturers.

Paul Graaf

Area Operations Manager, Europe

Issued by: LRQA Limited



liability is exclusively on the terms and conditions set out in that contract Issued by: LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom



Certificate identity number: 10508472

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Certificate Schedule

Location	Activities
Sperlingsgatan 5, 30248 Halmstad, Sweden	ISO 13485:2016 Design service company, developing software, electronics, and mechanics for medical device manufacturers.
Etteplan Finland Oy Ajajantie 1, 70780 Kuopio, Finland	ISO 13485:2016 Design service company, developing software, electronics, and mechanics for medical device manufacturers.
Etteplan Finland Oy Tekniikantie 4 D, 02150 Espoo, Finland	ISO 13485:2016 Design service company, developing software, electronics, and mechanics for medical device manufacturers.

