

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Neoventa Medical AB

Main Site: Norra Ågatan 32

SE- 431 35 Mölndal, Sweden (FIN F007622)

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

Design, manufacturing and distribution of products for perinatal care, including sterile leads. Installation and service of fetal monitors.

Certificate Number:

0194270

Revision Level: 00

Initial Certification Date:

2024-10-14

Date of Certification Decision:

2024-10-14

Certification Effective Date:

2024-10-14

Certification Expiry Date:

2027-10-13



intertek

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