

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

ABIGO Medical AB

Main Site: Vapenvägen 1, Askersund, Sweden 69633 (FIN F003656)

Additional site1: Smidesvägen 2, Askersund, Sweden 69633 (FIN F003656)

Additional site2: Mölndals bro 2, Mölndal, 431 31, Sweden (F007049)

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)

Brazil: RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

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)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act (as applicable)

The management system is applicable to:

Design, development, manufacturing and distribution of sterile wound dressings.

Main site: Production, Purchasing, Receiving, Storage

Additional site1: Storage

Additional site2: Management, Design

Certificate Number:

0079251-05

Initial Certification Date:

2018-08-06

Date of Certification Decision:

2024-07-31

Certification Effective Date:

2024-08-05

Certification Expiry Date:

2027-08-05



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