

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## ABIGO Medical AB

Main Site: Ekonomivägen 5,  
Askim, Sweden 43633 (FIN F000715)

Additional site1: Vapenvägen 1, Askersund, Sweden 69633 (FIN F003656)

Additional site2: Smidesvägen 2, Askersund, Sweden 69633 (FIN F003656)

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:** Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

**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

### The management system is applicable to:

*The Design, development, manufacture and distribution of sterile wound dressings and products for reducing symptoms associated with negative air pressure in the middle ear.*

*Additional site1: Production, Purchasing, Receiving, Storage*

*Additional site2: Storage*

**Certificate Number:**

0079251-01

**Initial Certification Date:**

2018-08-06

**Certification Effective Date:**

2021-08-05

**Certification Expiry Date:**

2024-08-05



**Intertek**

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