

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

ABIGO Medical AB

(DUNS # 35-610-8886)

Main Site: Ekonomivägen 5,
Askim, Sweden 43633

(DUNS # 77-619-2903)

Additional site: Vapenvägen 1, Askersund, Sweden 69639

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 OR 21 CFR 820.180 and 198, 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

Certificate Number:

0079251-00

Initial Certification Date:

2018-08-06

Certification Effective Date:

2018-08-06

Certification Expiry Date:

2021-08-05



Calin Moldoveanu

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