EC CERTIFICATION

EU Quality Management System Certificate

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

ABIGO Medical AB

Vapenvägen 1, SE-696 33 Askersund, Sweden

Manufacturer SRN: SE-MF-000000736

Scope:

Bacteria binding dressings

Certificate Number:
28620115063

Revision:
03

Initial Certification Date:
29 June 2021

Certificate Decision Date:
22 May 2026

Certificate Issue Date:
29 June 2026

Certificate Expiry Date:
28 June 2031

Mikael Hagelin
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Audit report reference	**Re-certification - ACTY-2021-471865**
Change notice reference	**CN00007-042 - Change in intended use**
	CN00007-045 - Addition of products
	CN00007-046 - Addition of products

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

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CERTIFICATE HISTORY

CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620115063	29 June 2021	Initial certificate
28620115063-01	12 August 2022	Change of address
28620115063-02	26 September 2022	Correction of SRN number
28620115063-03	22 May 2026	Re-certification

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