

EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

EU Regulation 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 EU Regulation 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:

28620115063-02

Initial Certification Date:

29 June 2021

Date of Certification Decision:

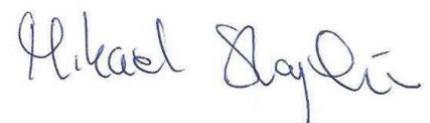
26 September 2022

Certificate Issue Date:

26 September 2022

Certificate Expiry Date:

28 June 2026



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

Technical Assessment Report Reference	N/A Change Notice CN00007-10
Last Audit report reference	N/A Change Notice CN00007-10

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

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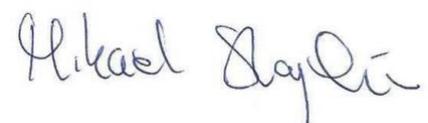
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CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620115063	29 June 2021	Initial certificate
28620115063-01	12 August 2022	Change of address



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