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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 restricted to the aspects relating to the conformity of the devices with sterility and metrological requirements - 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.

Certificate Number:
28620204971

Revision:
00

Initial Certification Date:
17 February 2025

Date of Certification Decision:
17 February 2025

Certificate Issue Date:
17 February 2025

Certificate Expiry Date:
22 February 2029

Alleva Medical Limited

Suite M-Q, 12th Floor, Kings Wing Plaza 2, 1 On Kwan St., Shek Mun, Shatin, N.T., Hong Kong SAR, China

Manufacturer SRN: CN-MF-000018963

Authorised Representative Name
MDSS GmbH
Schiffgraben, 41 30175 Hannover, Germany

Scope:

Sterility and metrology aspects of devices as detailed in attached product list.

Brian Mather
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.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The certificate remains the property of Intertek, to whom it must be returned upon request.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Last Audit report reference	**Stage 1 audit ACTY-2024-216825**
	Stage 2 audit ACTY-2024-216826
Change Notice reference	

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

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CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620204971	17 February 2025	Initial Certificate

PRODUCT LIST FOR CERTIFICATE

Issued to: Alleva Medical Limited

Certificate number: 28620204971

Certificate valid from: 2025-02-17

Product List Issue Date:
17 February 2025

Product	Classification and EMDN	Intended use[1]	Date Added
Class I sterile devices with a measuring function			
Basic UDI-DI: 489708907ST380PY			
ST380 - Vide® Three-Chamber Disposable Chest Drainage Unit (Water Seal)	Class I(s,m) A0601010201		2025-02-17
ST381 - Vide® Disposable Dry Suction/Water Seal Chest Drain	Class I(s,m) A0601010201		2025-02-17
ST382 - Vide® Disposable Dry Suction/Dry Seal Chest Drainage	Class I(s,m) A0601010201		2025-02-17
ST384 - Vide® Pediatric Dry Suction/Water Seal Chest Drain	Class I(s,m) A0601010201		2025-02-17
ST422 - Vide® Three-Chamber Disposable Pediatric Water Seal Chest Drain	Class I(s,m) A0601010201		2025-02-17
ST423 - Vide® Dual Chamber Dry Suction Water Seal Chest Drain	Class I(s,m) A0601010201		2025-02-17
ST425 - Vide® Breeze Chest Drain Valve	Class I(s,m) A0601010201		2025-02-17

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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.