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:
02

Initial Certification Date:
17 February 2025

Date of Certification Decision:
12 October 2026

Certificate Issue Date:
12 October 2026

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
Share Info GmbH
Am Schulzentrum 12, 41564 Kaarst, Germany

Scope:
Class I sterile Chest drain device and accessories and gravity enteral feeding bag devices

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.

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	**CN00292-011**
	CN00292-013

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
28620204971-01	24 November 2025	Change of Authorized Representative
28620204971-02	12 October 2026	Scope change

PRODUCT LIST FOR CERTIFICATE

Issued to: Alleva Medical Limited

Certificate number: 28620204971-02

Certificate valid from: 2026-10-12

Product list issue date:
12 October 2026

Product	Classification and EMDN	Intended use[1]	Date Added
Class I sterile devices			
Basic UDI-DI: 489708907ST220P9			
ST220-0001 - Sterile 600ml Gravity Enteral Feeding Bag	Class I(s) A080101		2026-10-09
Basic UDI-DI: 489708907ST295Q8			
ST295-0001 - Sterile 1200ml Gravity Enteral Feeding Bag	Class I(s) A080101		2026-10-09
ST295-0002 - Sterile 1200ml Gravity Enteral Feeding Bag	Class I(s) A080101		2026-10-09
Basic UDI-DI: 489708907ST380-0100PT			
ST380-0100 - 8-12 Fr Step-down Connector	Class I(s) EMDN: TBD		2026-10-09
Basic UDI-DI: 489708907ST380-0200PY			
ST380-0200 - Inline Needle-less Sampling Port Connector Set	Class I(s) EMDN: TBD		2026-10-09
Basic UDI-DI: 489708907ST380-0300Q5			
ST380-0300 - Patient Stepped Connector (16-40 Fr)	Class I(s) EMDN: TBD		2026-10-09
Basic UDI-DI: 489708907ST380-0400QA			
ST380-0400 - Y-Tubing Set for Dual Catheter Connection	Class I(s) EMDN: TBD		2026-10-09
Basic UDI-DI: 489708907ST380-0500QF			
ST380-0500 - Y-Tubing Set for Suction-Dual Drain Connection	Class I(s) EMDN: TBD		2026-10-09

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

Product	Classification and EMDN	Intended use[1]	Date Added
Basic UDI-DI: 489708907ST380-0600QL			
ST380-0600 - Transition Tube with Luer Connector	Class I(s) EMDN: TBD		2026-10-09
Basic UDI-DI: 489708907ST380-0700QR			
ST380-0700 - Manual Suction Bulb	Class I(s) EMDN: TBD		2026-10-09
Basic UDI-DI: 489708907ST380-0800QW			
ST380-0800 - Vac-Guard Suction Control Anti-Tampering Sticker	Class I(s) EMDN: TBD		2026-10-09
Basic UDI-DI: 489708907ST380-0900R3			
ST380-0900 - Sterile End cap for In-Line Connector	Class I(s) EMDN: TBD		2026-10-09
Basic UDI-DI: 489708907ST380PY			
ST380-0001 - Vide® Three-Chamber Disposable Chest Drainage Unit (Water Seal)	Class I(s) A0601010201		2025-07-17
ST380-0006 - Vide® Three-Chamber Disposable Chest Drainage Unit (Water Seal)	Class I(s) A0601010201		2025-07-17
ST380 - Vide® Three-Chamber Disposable Chest Drainage Unit (Water Seal)	Class I(s) A0601010201		2025-02-17
ST381-0001 - Vide® Disposable Dry Suction/Water Seal Chest Drain	Class I(s) A0601010201		2025-07-17
ST381 - Vide® Disposable Dry Suction/Water Seal Chest Drain	Class I(s) A0601010201		2025-02-17
ST382-0001 - Vide® Disposable Dry Suction/Dry Seal Chest Drainage	Class I(s) A0601010201		2025-07-17
ST382 - Vide® Disposable Dry Suction/Dry Seal Chest Drainage	Class I(s) A0601010201		2025-02-17
ST384-0001 - Vide® Pediatric Dry Suction/Water Seal Chest Drain	Class I(s) A0601010201		2025-07-17
ST384 - Vide® Pediatric Dry Suction/Water Seal Chest Drain	Class I(s) A0601010201		2025-02-17
ST422-0001 - Vide® Three-Chamber Disposable Pediatric Water Seal Chest Drain	Class I(s) A0601010201		2025-07-17

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

Product	Classification and EMDN	Intended use[1]	Date Added
ST422 - Vide® Three-Chamber Disposable Pediatric Water Seal Chest Drain	Class I(s) A0601010201		2025-02-17
ST423-0001 - Vide® Dual Chamber Dry Suction Water Seal Chest Drain	Class I(s) A0601010201		2025-07-17
ST423 - Vide® Dual Chamber Dry Suction Water Seal Chest Drain	Class I(s) A0601010201		2025-02-17
ST424-0001 - Vide® Pediatric Dry Suction/Water Seal Chest Drain	Class I(s) A0601010201		2025-07-17
ST425-0001 - Vide® Breeze Chest Drain Valve	Class I(s) A0601010201		2025-07-17
ST425 - Vide® Breeze Chest Drain Valve	Class I(s) A0601010201		2025-02-17
Basic UDI-DI: 489708907ST383Q6			
ST383-0001 - Vide® Disposable Dry Seal Chest Drainage	Class I(s) A0601010201		2026-10-09
Basic UDI-DI: 489708907ST428Q3			
ST428-0001 - Vide® BreezeXL Chest Drain Valve	Class I(s) A0601010201		2026-10-09
Basic UDI-DI: 489708907ST601-0001MN			
ST601-0001 - ThoraClear Chest Tube Clearance Device	Class I(s) A060201		2026-10-09
Basic UDI-DI: 489708907ST602-0001N3			
ST602-0001 - ThoraClear Chest Tube Clearance Device	Class I(s) A060201		2026-10-09



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