# 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.

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

**Certificate Number:**
28620204971

**Revision:**
01

**Initial Certification Date:**
17 February 2025

**Date of Certification Decision:**
24 November 2025

**Certificate Issue Date:**
24 November 2025

**Certificate Expiry Date:**
22 February 2029

Lian Zhang

Lian Zhang
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

| | |
|---|---|
| **Last Audit report reference** | **Stage 1 audit ACTY-2024-216825** |
| | **Stage 2 audit ACTY-2024-216826** |
| | |
| **Change Notice reference** | **CN00292-011** |
| | |

## CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

| |
|---|
| None |

## CERTIFICATE HISTORY

| PRECEDING CERTIFICATE NUMBER | DATE OF ISSUE | IDENTIFICATION OF CHANGES |
|---|---|---|
| 28620204971 | 17 February 2025 | Initial Certificate |
| 28620204971-01 | November 2025 | Change of Authorized Representative |
| | | |

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# PRODUCT LIST FOR CERTIFICATE

**Issued to:** Alleva Medical Limited

**Certificate number:** 28620204971-01

**Certificate valid from:** 2025-11-24

**Product list issue date:**
24 November 2025

| Product | Classification and EMDN | Intended use[1] | Date Added |
|---|---|---|---|
| **Class I sterile devices with a measuring function** | | | |
| **Basic UDI-DI: 489708907ST380PY** | | | |
| ST380-0001 - Vide® Three-Chamber Disposable Chest Drainage Unit (Water Seal) | Class I(s,m) A0601010201 | | 2025-07-17 |
| ST380-0006 - Vide® Three-Chamber Disposable Chest Drainage Unit (Water Seal) | Class I(s,m) A0601010201 | | 2025-07-17 |
| ST380 - Vide® Three-Chamber Disposable Chest Drainage Unit (Water Seal) | Class I(s,m) A0601010201 | | 2025-02-17 |
| ST381-0001 - Vide® Disposable Dry Suction/Water Seal Chest Drain | Class I(s,m) A0601010201 | | 2025-07-17 |
| ST381 - Vide® Disposable Dry Suction/Water Seal Chest Drain | Class I(s,m) A0601010201 | | 2025-02-17 |
| ST382-0001 - Vide® Disposable Dry Suction/Dry Seal Chest Drainage | Class I(s,m) A0601010201 | | 2025-07-17 |
| ST382 - Vide® Disposable Dry Suction/Dry Seal Chest Drainage | Class I(s,m) A0601010201 | | 2025-02-17 |
| ST384-0001 - Vide® Pediatric Dry Suction/Water Seal Chest Drain | Class I(s,m) A0601010201 | | 2025-07-17 |
| ST384 - Vide® Pediatric Dry Suction/Water Seal Chest Drain | Class I(s,m) A0601010201 | | 2025-02-17 |
| ST422-0001 - Vide® Three-Chamber Disposable Pediatric Water Seal Chest Drain | Class I(s,m) 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,m)<br>A0601010201 | | 2025-02-17 |
| ST423-0001 - Vide® Dual Chamber Dry Suction Water Seal Chest Drain | Class I(s,m)<br>A0601010201 | | 2025-07-17 |
| ST423 - Vide® Dual Chamber Dry Suction Water Seal Chest Drain | Class I(s,m)<br>A0601010201 | | 2025-02-17 |
| ST424-0001 - Vide® Pediatric Dry Suction/Water Seal Chest Drain | Class I(s,m)<br>A0601010201 | | 2025-07-17 |
| ST425-0001 - Vide® Breeze Chest Drain Valve | Class I(s,m)<br>A0601010201 | | 2025-07-17 |
| ST425 - Vide® Breeze Chest Drain Valve | Class I(s,m)<br>A0601010201 | | 2025-02-17 |

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