ALLEVA MEDICAL LTD.
Suite M-Q, 12th Floor, Kings Wing Plaza 2, 1 On Kwan St. Shek Mun, Shatin, N.T., Hong Kong
Tel: +852 3166 7200 Fax: +852 2355 7663 www.allevamedical.com

DECLARATION OF CONFORMITY

According to Article 19 of Regulation (EU) 2017/745 on Medical Devices, UK MDR 2002 and Medical Devices Ordinance (MedDO)

S R 8 1 2 . 2 1 3

Manufacture:	ALLEVA MEDICAL LIMITED
Address of Manufacturer:	Central Office: Suite M-Q, 12th Floor, Kings Wing Plaza 2, 1 On Kwan St. Shek Mun, Sha Tin, N.T., Hong Kong SAR, China Chinese Factory: (ALLEVA MEDICAL (D.G.) LIMITED) 76 San Lian Nan Road, Lu Wu Administration District, Changping Town, Dongguan City, Guangdong Province, China 523587
Single Registration Number (SRN):	CN-MF-000018963
EU Authorised Representative:	Share Info GmbH
Address of EU Authorised Representative:	Am Schulzentrum 12, 41564 Kaarst, Germany
Single Registration Number (SRN):	DE-AR-000005132
CH Authorised Representative:	Share Info Suisse GmbH
Address of CH Authorised Representative:	St. Leonhardstrasse 35, 9000 St. Gallen, Switzerland
Single Registration Number:	CHRN-AR-20002385
Name of GB Authorised Representative:	SHARE INFO LTD
Address of GB Authorised Representative:	3rd Floor, office C, Townend House, Park Street, Walsall, West Midlands, WS1 1NS, United Kingdom
Trade Name:	Vide®
Reference No.:	See Annex I
Accessories Reference No.:	See Annex II
Product Name:	Disposable Chest Drainage Series
Intended Use:	The device is intended to remove air and fluid from a patient's intrapleural cavity, such that the negative pressure normally present in the intrapleural cavity can be re-established and normal lung movement (expansion/contraction) can be restored.
Classification:	(EU) 2017/745 accord to Annex VIII, Rule 1, Class I (S, M)
Conformity Assessment	(EU) 2017/745 Medical Device Regulation Annex IX QMS

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Route:	
Basic UDI-DI:	489708907ST380PY
EMDN Code:	A0601010201 DRAINAGE SYSTEMS WITH ADJUSTABLE SUCTION AND COLLECTION CHAMBER
Notify Body:	Intertek Medical Notified Body AB
Address of Notified Body:	Torshamnsgatan 43, Box 1103 SE- 164 22 Kista Sweden
ID of the Notified Body:	CE 2862
Certification Number:	28620204971
Validity of the Certificate:	22 February 2029
Applicable Standards:	1. EN ISO 13485: 2016+A11 2. EN ISO 14971: 2019+A11 3. EN ISO 11135: 2014/A1: 2019 4. EN ISO 10993-7: 2008/AC: 2009 5. ISO/TR 24971: 2020 6. EN ISO 11737-1: 2018 7. EN ISO 11737-2: 2020 8. EN ISO 11138-1: 2017 9. EN ISO 11138-2: 2017 10. EN ISO 11607-1: 2020 11. EN ISO 11607-2: 2020 12. EN ISO 14644-1: 2015 13. EN ISO 14644-2: 2015 14. EN ISO 20417: 2021 15. MDR (EU) 2017/745 16. MEDDEV 2.7/1 rev.4 17. MEDDEV 2.12/1 rev.8 18. MEDDEV 2.12/2 rev.2 19. MDCG 2020-5 20. MDCG 2020-6 21. MDCG 2020-13 22. ISO 10079-3: 2022 23. ISO 10079-4: 2021 24. EN ISO 15223-1: 2021 25. ASTM D4169-22 26. ASTM F1980-21 27. EN 62366-1: 2015

As ALLEVA MEDICAL LIMITED, we declare under our sole responsibility that the devices (Disposable Chest Drainage Series) specified in Annex I covered by this declaration comply with the Regulation (EU) 2017/745 of the European Parliament, the UK MDR 2002, the Medical Devices Ordinance (MedDO) SR812.213 and of the Council on Medical Devices and that the requirements specified in the Regulation for these devices are fulfilled. Furthermore, the devices comply with the requirements of the applicable standards.

Place, Date of Issue : Dongguan, 20th, November, 2025

Signed by : KF Chan

Position : Quality Director

Signature and Stamp :

ALLEVA MEDICAL LIMITED

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Annex I - Reference No.

Product No.	REF No.	Dahlhausen ref code No.	Product Name
ST380	ST380-0001	04.700.01.380	Vide® Three-Chamber Disposable Chest Drainage Unit (Water Seal)
ST381	ST381-0001	04.701.01. 381	Vide® Disposable Dry Suction/Water Seal Chest Drain
ST382	ST382-0001	04.702.01.382	Vide® Disposable Dry Suction/Dry Seal Chest Drainage
ST422	ST422-0001	04.700.01.422	Vide® Three-Chamber Disposable Pediatric Water Seal Chest Drain
ST423	ST423-0001	04.701.02.423	Vide® Dual Chamber Dry Suction Water Seal Chest Drain

Annex II - Chest Drain Series Accessories

REF No.	Accessories Name
HC063-0001	Chest Drain Basket with Hanger + Clamp
HC063-0002	Chest Drain Basket with Clamp
ST380-0100	8-12 Fr Step-down Connector
ST380-0200	Inline Needle-less Sampling Port Connector Set
ST380-0300	Patient Stepped Connector (16-40 Fr)
ST380-0400	Y-Tubing Set for Dual Catheter Connection
ST380-0500	Y-Tubing Set for Suction-Dual Drain Connection
ST380-0600	Transition Tube with Luer Connector
ST380-0700	Manual Suction Bulb
ST380-0800	Vac-Guard Suction Control Anti-Tampering Sticker
ST380-0900	Sterile End cap for In-Line Connector