EU Declaration of Conformity

according to the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Doc. No.: LSMT-TF-VMVS-008-01

Manufacturer:	Guangzhou Landswick Medical Technologies Limited.
Address:	Room 1501, Room 1601, No.45, Ruiji Second Street, Huangpu Zone, 510530 Guangzhou, Guangdong, PEOPLE'S REPUBLIC OF CHINA
Single Registration Number (SRN) of the Manufacturer:	CN-MF-000022972
Authorised representative (AR):	Share Info GmbH
Address:	Am Schulzentrum 12, 41564 Kaarst, Germany
Single Registration Number (SRN) of AR:	DE-AR-000005132

We, the manufacturer, declare under our sole responsibility that:

the medical device(S)	**Product Name:**	Vacuum Mattress and Vacuum Splint
	Type/model, identification of product allowing traceability (Where applicable):	*Refer to the Appendix II for details.*
	EMDN Code:	V08050199
	Intended Purpose:	The vacuum mattresses are designed to fix and immobilize patients suspected of having spinal fractures and hurt of broken extremities. The Landswick vacuum mattresses are not suitable for permanent immobilization as is the case with a plaster. The Landswick vacuum splints are designed to fix and immobilize patients suspected of having spinal fractures and hurt of broken extremities. The Landswick vacuum splints are not suitable for permanent immobilization as is the case with a plaster.
	Classification: (Annex VIII of the MDR)	Class I according to Rule 1.
	Basic UDI-DI:	*Refer to the Appendix III for details.*
Conformity assessment procedure:		EU Declaration of Conformity + Technical Documentation (Annex II) of Regulation (EU) 2017/745
Applied harmonized standards and Common Specification:		*Refer to the Appendix I for details.*

Appendix I: Applied harmonized standards and Common Specification

is/are in conformity with the relevant provisions and requirements of the Council and the parliament regulation (EU) 2017/745 for medical device and all applicable harmonized standards and Common Specification. All supporting documents are retained under the premises of the manufacturer.

Applied harmonized standards and Common Specification	Regulation (EU) 2017/745: 2017	EN ISO 10993-1:2020
	EN ISO 13485:2016 + AC:2018 + A11:2021	EN ISO 10993-5:2009
	EN ISO 14971: 2019	EN ISO 10993-10:2023
	EN ISO/TR 24971: 2020	EN ISO 10993-23:2021
	EN ISO 15223-1: 2021	EN 1865-1: 2010 + A1: 2015
	EN ISO 20417: 2021	

This DoC is valid from 2025.08.22.

Authorized by:

Lin Xiaomei

Signature (on behalf of the manufacturer)

Position: General Manager

Signed on: 2025.08.22.

Place: Guangdong, China

CE

Appendix II: Model

Product Name	Model
Vacuum Mattress	VMA-0A10, VMA-0A10D, VMA-1A00, VMA-1B00, VMA-1B00D, VMA-1B01, VMA-1B01D, VMA-1B02, VMA-1B04, VMA-0B00, VMA-0B00D, VMA-0B01, VMA-0B01D, VMA-0B02, VMA-0B02D, VMA-0B03, VMA-0B04D, VMA-0C00, VMA-0C01, VMA-0A00, VMA-0A00D, VMA-0A20, VMP-0B00, VMP-0B00D, VMP-0A00, VMP-0A00D, VMP-0A10
Vacuum Splint	VSA-2A00, VSA-2A10, VSA-2A01, VSA-2B00, VSA-2B01, VSA-2C00, VSA-3A00, VSA-3A01, VSA-3A02, VSA-3B00, VSA-3B02, VSA-3B03, VSA-3C00, VSA-4A00, VSA-4A01, VSA-4A02, VSA-4A03, VSA-4B00, VSA-4B01, VSA-4B02, VSA-4C00, VSA-5A00, VSA-5A01, VSA-5A02, VSA-5A04, VSA-5A05, VSA-5C00, VSA-6B00, VSA-6B01, VSA-6B02, VSA-6C00, VSA-7B00, VSA-7B01, VSA-7B02, VSA-7B03, VSA-7B04, VSA-7B05, VSA-7B06, VSA-7B07, VSA-7C00, VSA-8A00, VSA-8B01, VSA-8B02, VSA-9B01, VSA-9B02, LSK-2A00, LSK-2A01, LSK-3A00, LSK-3A01, LSK-3B00, LSK-3B01, LSK-4A00, LSK-4A01, LSK-5A00, LSK-5A01

Appendix III: Basic UDI-DI

Product Name	Model	Basic UDI-DI
Vacuum Mattress	VMA-0A10	69749621VMA-0A102W
	VMA-0A10D	69749621VMA-0A10DBW
	VMA-1A00	69749621VMA-1A0032
	VMA-1B00	69749621VMA-1B0037
	VMA-1B00D	69749621VMA-1B00DCB
	VMA-1B01	69749621VMA-1B0139
	VMA-1B01D	69749621VMA-1B01DCE
	VMA-1B02	69749621VMA-1B023B
	VMA-1B04	69749621VMA-1B043F
	VMA-0B00	69749621VMA-0B002Y
	VMA-0B00D	69749621VMA-0B00DBY
	VMA-0B01	69749621VMA-0B0132
	VMA-0B01D	69749621VMA-0B01DC3
	VMA-0B02	69749621VMA-0B0234
	VMA-0B02D	69749621VMA-0B02DC6
	VMA-0B03	69749621VMA-0B0336
	VMA-0B04D	69749621VMA-0B04DCC
	VMA-0C00	69749621VMA-0C0035
	VMA-0C01	69749621VMA-0C0137
	VMA-0A00	69749621VMA-0A002T
	VMA-0A00D	69749621VMA-0A00DBR
	VMA-0A20	69749621VMA-0A202Z
	VMP-0B00	69749621VMP-0B0093
	VMP-0B00D	69749621VMP-0B00DKX
	VMP-0A00	69749621VMP-0A008W
	VMP-0A00D	69749621VMP-0A00DKQ
	VMP-0A10	69749621VMP-0A108Z
Vacuum Splint	VSA-2A00	69749621VSA-2A006F
	VSA-2A10	69749621VSA-2A106J
	VSA-2A01	69749621VSA-2A016H
	VSA-2B00	69749621VSA-2B006L
	VSA-2B01	69749621VSA-2B016N
	VSA-2C00	69749621VSA-2C006R
	VSA-3A00	69749621VSA-3A006N
	VSA-3A01	69749621VSA-3A016Q
	VSA-3A02	69749621VSA-3A026S
	VSA-3B00	69749621VSA-3B006T
	VSA-3B02	69749621VSA-3B026X
	VSA-3B03	69749621VSA-3B036Z
	VSA-3C00	69749621VSA-3C006Y

	VSA-4A00	69749621VSA-4A006V
	VSA-4A01	69749621VSA-4A016X
	VSA-4A02	69749621VSA-4A026Z
	VSA-4A03	69749621VSA-4A0373
	VSA-4B00	69749621VSA-4B0072
	VSA-4B01	69749621VSA-4B0174
	VSA-4B02	69749621VSA-4B0276
	VSA-4C00	69749621VSA-4C0077
	VSA-5A00	69749621VSA-5A0074
	VSA-5A01	69749621VSA-5A0176
	VSA-5A02	69749621VSA-5A0278
	VSA-5A04	69749621VSA-5A047C
	VSA-5A05	69749621VSA-5A057E
	VSA-5C00	69749621VSA-5C007E
	VSA-6B00	69749621VSA-6B007G
	VSA-6B01	69749621VSA-6B017J
	VSA-6B02	69749621VSA-6B027L
	VSA-6C00	69749621VSA-6C007M
	VSA-7B00	69749621VSA-7B007P
	VSA-7B01	69749621VSA-7B017R
	VSA-7B02	69749621VSA-7B027T
	VSA-7B03	69749621VSA-7B037V
	VSA-7B04	69749621VSA-7B047X
	VSA-7B05	69749621VSA-7B057Z
	VSA-7B06	69749621VSA-7B0683
	VSA-7B07	69749621VSA-7B0785
	VSA-7C00	69749621VSA-7C007U
	VSA-8A00	69749621VSA-8A007R
	VSA-8B01	69749621VSA-8B017Y
	VSA-8B02	69749621VSA-8B0282
	VSA-9B01	69749621VSA-9B0187
	VSA-9B02	69749621VSA-9B0289
	LSK-2A00	69749621LSK-2A004K
	LSK-2A01	69749621LSK-2A014M
	LSK-3A00	69749621LSK-3A004S
	LSK-3A01	69749621LSK-3A014U
	LSK-3B00	69749621LSK-3B004X
	LSK-3B01	69749621LSK-3B014Z
	LSK-4A00	69749621LSK-4A004Z
	LSK-4A01	69749621LSK-4A0153
	LSK-5A00	69749621LSK-5A0058
	LSK-5A01	69749621LSK-5A015A