## **EU Declaration of Conformity**

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

COUNCIL

## Doc. No. XSTO-CE-T01-008-01

On the basis of the referenced test report(s), sample(s) tested of the below product have been found to comply with the standards harmonized with the directives listed on this verification at the time the tests were carried out. Other standards and Directives may be relevant to the product. This verification is part of the full test report(s) and should be read in conjunction with it <them>.

Manufacturer:		XSTO CO., LTD.
Address:		Floor 1, Building C, 555 Plant, Ma'an Cun Rd, Cuiheng New
		District, Zhongshan City, Guangdong Province, China
Single Registration Number		CN-MF-000018902
(SRN) of the Manufacturer:		
Authorised representative (AR):		Share Info GmbH
Address:		Heerdter Lohweg 83, 40549 Düsseldorf
Single Registration Number		DE-AR-000005132
(SRN) of AR:		
We, the manufacturer, declare under our sole responsibility that:		
the medical device(S)	Product	Stair climber for wheelchair
	Name:	
	Type/model,	
	identification of	TR250T
	product allowing	
	traceability	
	(Where applicable):	
	EMDN Code:	Y183099
	Intended Purpose:	The stair climber for wheelchair is a wheelchair climbing equipment, which can be used after being directly connected with the manual wheelchair. It can easily solve the inconvenience problem of wheelchair users up and down stairs.
	<b>Classification:</b>	
	(Annex VIII of	Class I Medical Device according to rule 13
	the MDR)	
	Basic UDI-DI:	/
Conformity assessment		EU Declaration of Conformity + Technical Documentation
procedure:		(Annex II)
Applied harmonized standards and Common Specification:		Refer to the Appendix I for details.

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## 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) 2017/745:2023 Regulation 1907/2006: 2023 EN ISO 14971: 2019/A11: 2021 ISO/TR 24971: 2020 EN ISO 13485: 2016+AC: 2018 EN ISO 20417: 2021 EN ISO 15223-1: 2021 EN ISO 10993-1: 2020 EN ISO 10993-5: 2009 EN ISO 10993-10: 2023 EN 62366-1: 2015+AC:2015+AC:2016+A1: 2020 EN 60601-1-2: 2015+A1:2020 EN 60601-1-6: 2010+A1:2015+A2:2020 ISO 7176-28: 2012 IEC 62133-2:2017 IEC 62133-2:2017+AMD1:2021

CE

This DoC is valid from Nov. 15, 2023. Authorized by:

Yong Zhan

Signature (on behalf of the manufacturer) Position: General Manager Rev. 1.1 Signed on: Nov. 15, 2023. Place: Dongguan, China

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