

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 (SRN) of the Manufacturer:	CN-MF-000018902
Authorised representative (AR):	Share Info GmbH
Address:	Heerdter Lohweg 83, 40549 Düsseldorf
Single Registration Number (SRN) of AR:	DE-AR-000005132

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

the medical device(S)	Product Name:	Stair climber for wheelchair
	Type/model, identification of product allowing traceability (Where applicable):	TR250T
	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.
	Classification: (Annex VIII of the MDR)	Class I Medical Device according to rule 13
	Basic UDI-DI:	/
Conformity assessment procedure:	EU Declaration of Conformity + Technical Documentation (Annex II)	
Applied harmonized standards and Common Specification:	<i>Refer to the Appendix I for details.</i>	

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

This DoC is valid from Nov. 15, 2023.

Authorized by:

Yong Zhao



Signature (on behalf of the manufacturer)

Position: General Manager

Rev. 1.1

Signed on: Nov. 15, 2023.

Place: Dongguan, China