EU Declaration of Conformity

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

Doc. No.: XSTO-CE-T02-008-01

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:**	Powered wheelchair (mobility robot)
	Type/model, identification of product allowing traceability (Where applicable):	M4, M4U
	EMDN Code:	Y122127
	Intended Purpose:	The Powered wheelchair (mobility robot) is a motor driven transportation suitable for medical institutions or families as people with mobility difficulties.
	Classification: (Annex VIII of the MDR)	Class I Medical Device according to rule 13
	Basic UDI-DI:	697505265M4YV
Conformity assessment procedure:		EU Declaration of Conformity + Technical Documentation (Annex II)
Applied harmonized standards and Common Specification:		*Refer to the Appendix I for details.*
Notified Body:		--
Address:		--
Notified Body number:		--
Certificate(s) number.:		--

Expire date of the Certificate:	--
Start of CE Marking:	--

The product concerned has been manufactured under a quality management system according to Annex IX of Regulation (EU) 2017/745.

The above-mentioned declaration of conformity was prepared by following the Annex IV of Regulation (EU) 2017/745 and is exclusively under the responsibility of the manufacturer.

XSTO CO., LTD.

Floor 1, Building C, 555 Plant, Ma'an Cun Rd, Cuiheng New District, Zhongshan City, Guangdong Province, China

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	EN ISO 10993-5: 2009
	MEDDEV 2.7/1 rev.4:2016	EN ISO 10993-10: 2023
	MEDDEV2.12/1-rev.8:2013	EN ISO 10993-23: 2021
	EN ISO 14971: 2019/A11: 2021	EN 12184: 2022
	ISO/TR 24971: 2020	EN 62133-2: 2017/A1: 2021/AC: 2022-01
	EN ISO 13485: 2016+AC: 2018	EN 60601-1-2: 2015+A1:2020
	EN 20417: 2021	EN 62304:2006/A1:2015
	EN ISO 15223-1: 2021	
	EN ISO 10993-1: 2020	

This DoC is valid from 2024. 07. 03.

Authorized by:

Yong Zhao

Signature (on behalf of the manufacturer)

Position: General Manager

Rev.: 2.0

Signed on: 2024. 07. 03.

Place: Zhongshan, China

CE