

EU Declaration of Conformity

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

Doc. No.: XSTO-CE-T04-DOC-01

Manufacturer: XSTO CO., LTD.
Floor 9, Building No.1, Cuiheng Technology Intelligent
Address: Hub, No.1 Heji Street, Cuiheng New District, Zhongshan
City, Guangdong, China

**Single Registration
Number (SRN) of the
Manufacturer:** CN-MF-000018902

**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:	Powered wheelchair (mobility robot)
	Type/model, identification of product allowing traceability	XSTO M4 Pro
	(Where applicable): EMDN Code:	Y122127-ELECTRIC WHEELCHAIRS
	Intended Purpose:	The Powered wheelchair (mobility robot) is a motor driven transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position and it is suitable for use by people with mobility difficulties in medical institutions or home settings.
	Classificatio n: (Annex VIII of the MDR)	Class I Medical Device according to rule 13
	Basic UDI-DI:	697505265XSTOM4ProQ6
	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>
	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 9, Building No.1, Cuiheng Technology Intelligent Hub, No.1 Heji Street, Cuiheng New District, Zhongshan City, Guangdong, China

Appendix I: Applied harmonized standards, 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, standards and Common Specification. All supporting documents are retained under the premises of the manufacturer.

Applied harmonized standards, standards and Common Specification:

EN ISO 14971: 2019 + A11: 2021
CEN ISO/TR 24971: 2020
EN ISO 13485: 2016 +AC: 2018 + A11: 2021
EN ISO 20417: 2021
EN ISO 15223-1: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009 + A11: 2025
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021 + A1: 2025
EN 12184: 2022
EN 62133-2: 2017 + A1: 2021 + AC: 2022-01
EN 60601-1-2: 2015 + A1: 2021
EN 60601-1-6: 2010 + A1: 2015 + A2: 2021
EN 62304: 2006 + A1: 2015
EN 62366-1: 2015 + AC: 2015 + AC: 2016-09 + A1: 2020

This DoC is valid from 2025.10.23.

Authorized by:




Signature (on behalf of the manufacturer)

Position: General Manager

Rev.: 1.0

Signed on: 2025.10.23

Place: Zhongshan, China

