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

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 9, Building No.1, Cuiheng Technology Intelligent 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 (Where applicable):	M4B, M4, M4U
	EMDN Code:	Y122127-ELECTRIC WHEELCHAIRS
	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		*Refer to the Appendix I for details.*

standards, standards and Common Specification:

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: 2026 EN ISO 15223-1: 2021+A1: 2025 EN ISO 10993-1: 2025 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: 2006 + A1: 2013 + AC: 2014 + A12: 2014 +A2: 2021 + AC: 2022-12 + A13: 2024 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 ISO 16840-10: 2021 + Amd 1: 2024

This DoC is valid from 2026.05.22.

Authorized by:

Signature (on behalf of the manufacturer)

Position: General Manager

Rev.: 2.2

Signed on: 2026.05.22.

Place: Zhongshan, China

CE

Appendix II: Revision records

Effective Date	Revision	Revised Content	Notes
2024-02-04	V1.0	First issue	/
2024-05-15	V1.1	Updated product name	/
2024-07-03	V2.0	Updated the product name in the intended use	/
2025-05-09	V2.1	Updated European Representative address	/
2026-05-22	V2.2	Updated Type/model and Appendix I	/