Declaration of Conformity 2023-02 Axion Rotary Interface

This Declaration of Conformity is in accordance with the European Standard EN ISO/IEC 17050-1:2010 "Conformity assessment – supplier's declaration of conformity", and is issued under the sole responsibility of Symmetric Designs Ltd.

Basic UDI-DI: Wheelchair Accessories - 81648488888-7

PRODUCT IDENTIFICATION	
Product Name and Intended Purpose	**Model Number (and UDI-DI)**
Axion Rotary Interface To facilitate the rotation of the head through rotation of a wheelchair headrest Intended Users: Wheelchair users	AXION 6019 (81648400171), AXION 6025 (81648400172), AXION 9019 (81648400174), AXION 9025 (81648400175), AXION 60R82 (81648401177), AXION 90R82 (81648401178), AXION RB (81648401176)
Authorized Representative	**Telephone/email**
MedEnvoy Global B.V. Prinses Margrietplantsoen 33 – Suite 123 2595 AM The Hague, The Netherlands	+31.70.326.2148 - phone info@medenvoyglobal.com

CONFORMITY ASSESSMENT	
Device classification	**Route to compliance**
Class 1 Rule 1	Regulation (EU) 2017/745 of The European Parliament and of the Council

Symmetric Designs Ltd. declares that the products meet the provision of the Regulation (EU) 2017/745 of The European Parliament and of the Council as transposed in the national laws of the Member States; and that the products meet the following standards:

Standards	Description
EN ISO 14971:2019	Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Symbols to be used with medical device labels and labelling
EN 62366	Application of Usability Engineering to Medical Devices
EN 1041:2008	Information to be supplied by the Manufacturer of Medical Devices

SIGNATURE: 

COMPANY REPRESENTATIVE: Samuel Hannah

PLACE OF ISSUE: Salt Spring Island, BC, Canada

TITLE: CEO

DATE: 2023-03-30

Manufacturer Name and Address: Symmetric Designs Ltd., 125 Knott Place, Salt Spring Island, B.C., V8K 2M4, Canada

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