

Declaration of Conformity 2020-02 Axion Rotary Interface

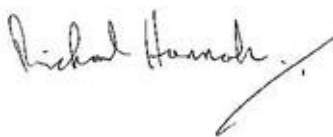
This Declaration of Conformity is in accordance with the European Standard EN ISO/IEC 17050-1:2010 "Conformity assessment – supplier's declaration of conformity".

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 (81648400170), Axion 9025 (81648400174), Axion 60R82 (81648400175), Axion 90R82(81648400173)
Authorized Representative	Telephone/email
Emergo Europe Prinsessegracht 20 2514 AP The Hague, The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.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 14971:2012	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: Richard Hannah

PLACE OF ISSUE: Salt Spring Island, BC, Canada

TITLE: President

DATE: 2020-05-22

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

125 Knott Place, Salt Spring Island, BC V8K 2M4 CANADA