Declaration of Conformity 2020-09 Savant Headrest

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)**
Savant Headrest Intended Use: To support the head of the occupant when seated in a wheelchair Intended Users: Wheelchair users	Savant-A (81648400130), Savant-A-T (81648400139), Savant-A-TB (81648400542), Savant-A-TM (81648400545), Savant-A-HB (81648400150), Savant-P (81648400132), Savant-P-T (81648400141), Savant-P-TB (81648400544), Savant—P-TM (81648400547), Savant-S (81648400131), Savant-S-T (81648400140), Savant—S-TB (81648400543), Savant—S-TM (81648400546), Savant—SP (81648400152),
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