

Declaration of Conformity 2023-09 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”, and is issued under the sole responsibility of Symmetric Designs Ltd.

BASIC UDI-DI: Wheelchair Accessory - 81648488888-7

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-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), SAVANTCC-A (81648400587), SAVANTCC-A-T (81648400588), SAVANTCC-A-TM (81648400589), SAVANTCC-A-TB (81648400590), SAVANTCC-S (81648400591), SAVANTCC-S-T (81648400592), SAVANTCC-S-TM (81648400593), SAVANTCC-S-TB (81648400594), SAVANTCC-P (81648400595), SAVANTCC-P-T (81648400596), SAVANTCC-P-TM (81648400597), SAVANT-P-TB (81648400598), SAVANTCC-SP (81648400600)
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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