

Declaration of Conformity 2023-10 Respira Backrest

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)
Respira Backrest To support the user when seated in a wheelchair Intended Users: Wheelchair users.	See attached Appendix I
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: 2023-11-23

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

RBS1210	81648402180	RBS1216-EXT	81648402025	RBD1820	81648402070	RBC1414-BA	81648402115
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