

Declaration of Conformity 2023-07 Wheelchair Headrest Hardware

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)
Wheelchair Headrest Hardware To provide a mechanical link between a wheelchair headrest and a wheelchair. Intended Users: Wheelchair Users	See attached Appendix 1
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

STRP	81648400691	TWIN-STOPRING	81648400552
STRP 15SQ	81648400692	TWIN FLIP19	81648400553
STRP 12SQ	81648400693	TWIN FLEX CON-KIT	81648400554
NA-150	81648400160	TWIN MB	81648400555
NA-250	81648400161	TWIN FLEX19 15SQ	81648400556
WA-19	81648400162	TWIN FLIP FLEX 15SQ	81648400557
SSR82	81648400163	TWIN FLIP FLEX19 15SQ	81648400558
SS-R82-25	81648400164	TWIN DYN 19	81648400559
TWIN HH	81648400165	TWIN FLEX 12SQ	81648400560
TWIN HH2	81648400166	INF LINK	81648400561
TWIN FLEX	81648400167	TWIN HH 12SQ	81648400562
TWIN AH	81648400168	APEX HH-XHS	81648400563
TWIN DYN	81648400169	D-WHFR-SL	81648400565
TWIN HH19	81648400176	CHA-ADAPT	81648400566
APEX HH	81648400177	TWIN BALL 19	81648400599
TWIN DYN-FLIP	81648400178	TWIN MB 15SQ	81648400605
TWIN DYN-FLIP 15SQ	81648400179	TWIN DYN-FLIP FLEX	81648400606
TWIN DYN-FLIP19	81648400180	TWIN FLIP 12SQ	81648400694
TWIN DYN-FLIP19 15SQ	81648400181	APEX MB	81648400695
TWIN HH 15SQ	81648400182	CHAL-LEVER	81648400548
TWIN HH19 15SQ	81648400183	CHAM-LEVER	81648400549
TWIN FLEX 15SQ	81648400184	CHAS-LEVER	81648400550
TWIN DYN 15SQ	81648400185	CHAL-KNOB	81648400697
TWIN DYN19 15SQ	81648400186	CHAM-KNOB	81648400698
TWIN FLIP 15SQ	81648400187	CHAS-KNOB	81648400699
TWIN FLIP19 15 SQ	81648400188		
INF HH	81648400189		
TWIN FLIP	81648400190		
TWIN FLIP FLEX	81648400191		
TWIN FLEX19	81648400192		
D-WHFR	81648400551		

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