

Declaration of Conformity 2020-07 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”.


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	APEX HH (816484400177), CHAL(816484400548), CHAM(816484400549), CHAS(816484400550), INF HH (816484400189), INF LINK(), NA-150(816484400160), NA-250(816484400161), SS-R82-25 (816484400164), SSR82 (816484400163), TWIN AH(816484400168), TWIN-STOPRING ((816484400552), TWIN DYN(816484400169), TWIN DYN-FLIP(816484400178), TWIN DYN-FLIP 15SQ(816484400179), TWIN DYN-FLIP19(816484400180), TWIN DYN-FLIP 19 15SQ(816484400181), TWIN DYN 15SQ(816484400185), TWIN DYN 19 15SQ(816484400186), TWIN FLEX(816484400167),TWIN FLEX 15SQ(816484400184), TWIN CON-KIT(816484400554),, TWIN FLEX 19(816484400192), TWIN FLEX 19 15SQ(816484400556), TWIN FLIP(816484400190), TWIN FLIP 15SQ(816484400187), TWIN FLIP FLEX(816484400191), TWIN FLIP FLEX 15SQ(816484400557), TWIN FLIP FLEX19(816484400558), TWIN FLIP FLEX19 15SQ(816484400559), TWIN FLIP19(816484400553), TWIN FLIP19 15SQ9(816484400188), TWIN HH(816484400165), TWIN HH 15SQ(816484400182), TWIN HH 19(816484400176), TWIN HH19 15SQ(816484400183), TWIN HH2(816484400166), TWIN MB(816484400555), WA-19(816484400162)
Authorized Representative	Telephone/email
Emergo Europe Prinsessegracht 20 2514 AP The Hague, The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

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

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

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