

Declaration of Conformity 2020-03 Free Form Seating

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)
Free Form Seating To provide a contoured wheelchair seat or backrest for wheelchair users Intended Users: Wheelchair users	FF2BU(81648400412), FF2BU25(81648400420), FFA2BU(81648400446), FFAB2-8(81648400447), FFAS1(81648400403), FFAS2(81648400404), FFAS3(81648400424), FFBC1(81648400448), FFBC1-ST(81648400452), FFBC2(81648400449), FFBC2-ST(81648400453, FFBC3(81648400450), FFBC3-ST(81648400454), FFCUST-01CM(81648400400), FFCUST-01CM/ST(81648400462), FFCUST-01IND(81648400443), FFCUST-01IND/ST(81648400465), FFCUST-01NH(81648400471), FFCUST-02CM(81648400401), FFCUST-02CM/ST(81648400463), FFCUST-02IND(81648400444), FFCUST-02IND/ST(81648400466), FFCUST-02NH(81648400472), FFCUST-03CM(81648400402), FFCUST-03CM/ST(81648400464), FFCUST-03IND(81648400445), FFCUST-03IND/ST(81648400467), FFCUST-03NH(), FFCC(), FFCC-STIM(), FFCC2(), FFCLA(81648400411), FFCUST-BASEKIT(), FFCUST-ESSKIT, FFCUST-FFKIT(81648400421), FFCUST-FFKIT(A), FFCUST-FFKIT(ADP), FFCUST-FFKITST(), FFCUST-FFKIT/ST(CUST), FFCUST-FFKIT/ST(FD), FFCUST-LB01(81648400433), FFCUST-LB01/ST(81648400468), FFCUST-LB02(81648400434), FFCUST-LB02/ST(81648400469), FFCUST-LB03(81648400435), FFCUST-LB03/ST(81648400470), FFEDB(81648400413), FFEDB35(81648400419), FFFPM(81648400422), FFHAL(81648400405), FFHAM(81648400406), FFHAS(81648400407), FFHASX(81648400408), FFHASXX(81648400473), FFHMP(81648400414), FFIND(81648400417), FFLBC1(81648400455), FFLBC1/ST(81648400458), FFLBC2(81648400456), FFLBC2/ST(81648400459), FFLBC3(81648400457), FFLBC3/ST(81648400460), FFLBSHELL01(81648400474), FFLBSHELL02(81648400475), FFLBSHELL03(816484004376), FFMBT(81648400409), FFSHELL01(81648400430), FFSHELL02(81648400431), FFSHELL03(81648400432), FFSMT20(81648400427), FFSMT50(81648400428), FFSTAY(81648400416), FFSTIM(81648400451), FFUPH(81648400425), FFUPH-ST(81648400461), FFUPH2(81648400426), FFVER(81648400418), FFWCC(81648400410)
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

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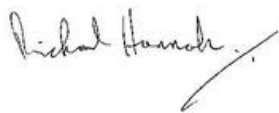
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CONFORMITY ASSESSMENT	
Device classification	Route to compliance
Class 1 Rule 1	Regulation (EU) 2017/745 of The European Parliament and of the Council

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 14971:2012	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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