

Declaration of Conformity 2023-03 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”, 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)
Free Form Seating To provide a contoured wheelchair seat or backrest for wheelchair users 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	Symbolstobeused 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

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

FFAS1	81648400403	FFCUST-LB03	81648400435
FFAS2	81648400404	FFBCUST-01IND	81648400443
FFHAL	81648400405	FFBCUST-021IND	81648400444
FFHAM	81648400406	FFBCUST-03IND	81648400445
FFHAS	81648400407	FFA2BU	81648400446
FFHAXS	81648400408	FFA2BU-8	81648400447
FFMBT	81648400409	FFBC1	81648400448
FFWCC	81648400410	FFBC2	81648400449
FFCLA	81648400411	FFBC3	81648400450
FF2BU	81648400412	FFSTIM	81648400451
FFEDB	81648400413	FFBC1-ST	81648400452
FFHMP	81648400414	FFBC2-ST	81648400453
FFJIG	81648400415	FFBC3-ST	81648400454
FFSTAY	81648400416	FFLBC1	81648400455
FFVER	81648400418	FFLBC2	81648400456
FFEDB35	81648400419	FFLBC3	81648400457
FF2BU25	81648400420	FFLBC1-ST	81648400458
FFKIT	81648400421	FFLBC2-ST	81648400459
FFFPM (x2)	81648400422	FFLBC3-ST	81648400460
FFSTAY (x6)	81648400423	FFUPH-ST	81648400461
FFAS3	81648400424	FFBCUST-01CM/ST	81648400462
FFUPH	81648400425	FFBCUST-02CM/ST	81648400463
FFUPH2	81648400426	FFBCUST-03CM/ST	81648400464
FFSMT20	81648400427	FFBCUST-01IND/ST	81648400465
FFSMT50	81648400428	FFBCUST-021IND/ST	81648400466
FFSHELL01	81648400430	FFBCUST-03IND/ST	81648400467
FFSHELL02	81648400431	FFCUST-LB01/ST	81648400468
FFSHELL03	81648400432	FFCUST-LB02/ST	81648400469
FFCUST-LB01	81648400433	FFCUST-LB03/ST	81648400470
FFCUST-LB02	81648400434	FFBCUST-01NH	81648400471

FFBCUST-02NH	81648400472	FFM5XSS-50	81648400707
FFHASXX	81648400473	FFBCUST-03IND/NC	81648400708
FFLBSHELL01	81648400474	FF VELA	81648400709
FFLBSHELL02	81648400475	FFFA	81648400710
FFLBSHELL03	81648400476	FFBCUST-03IND/FPM	81648400711
FFCUST-BASEKIT	81648400477	FFFA	81648400712
FFIND	81648400478		
FFSTAY-10	81648400479		
FFBCUST-XL	81648400480		
FFBCUST-XXL	81648400481		
FFCUST-ESSKIT	81648400482		
FFCUST-FFKIT/ST	81648400483		
FFCUST-LB03K	81648400484		
FFECC	81648400485		
FFSHELLXL	81648400486		
FFSHELLXXL	81648400487		
FFARRAY	81648400488		
FFBCUST-LB01-NH	81648400489		
FFM5SS-500	81648400490		
FFBCXL	81648400491		
FFBCXXL	81648400492		
FFBCUST-XL/NC	81648400493		
FFBCUST-03NH	81648400494		
FFSTIM-AIR	81648400498		
FFIND-FPM	81648400700		
FFBCUST-XL/FPM	81648400701		
FFBCUST-01NH/ST	81648400703		
FFBCUST-CUST-IND	81648400704		
FFBCUST-CUST-CM	81648400705		
FFM5SS-50	81648400706		