

Declaration of Conformity 2023-03 Lateral Upper Body Support (L.U.B.S.)

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)
Lateral Upper Body Supports (L.U.B.S) Intended Use: To provide support and control for the body in seated position within a wheelchair	See attached Appendix 1
Intended Users: Wheelchair users	

Authorized Representative	Telephone/email
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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 14971:2019	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: 2023-11-01

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

LUBSFFAH-RBP	81648400726	LUBSFF3F-LCM	81648400765
LUBSFFAH-LBP	81648400727	LUBSFF3F-RCM	81648400766
LUBSFFAH-RCM	81648400729	LUBSFF3F-LBP	81648400767
LUBSFFAH-LCM	81648400730	LUBSFF3F-RBP	81648400768
LUBSFF4S-LBP	81648400731	LUBSFF4F-LCM	81648400769
LUBSFF5S-LBP	81648400732	LUBSFF4F-RCM	81648400770
LUBSFF7S-LBP	81648400733	LUBSFF4F-LBP	81648400771
LUBSFF10S-LBP	81648400734	LUBSFF4F-RBP	81648400772
LUBSFFCUST-BP	81648400735	LUBSFF5F-LCM	81648400773
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LUBSFFCUST-CM	81648400741	LUBSFF7F-RCM	81648400778
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LUBSFF10S-RBP	81648400750		
LUBSFF4S-RCM	81648400751		
LUBSFF5S-RCM	81648400752		
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LPAD34-L	81648402801	LUBS35-LBP	81648402831
LPAD35-L	81648402802	LUBS35-RBP	81648402832
LPAD45-L	81648402803	LUBS45-LCM	81648402833
LPAD46-L	81648402804	LUBS45-RCM	81648402834
LPAD56-L	81648402805	LUBS45-LBP	81648402835
LPAD34-R	81648402806	LUBS45-RBP	81648402836
LPAD35-R	81648402807	LUBS46-LCM	81648402837
LPAD45-R	81648402808	LUBS46-RCM	81648402838
LPAD46-R	81648402809	LUBS46-LBP	81648402839
LPAD56-R	81648402810	LUBS46-RBP	81648402840
LUBSCOV34-L	81648402811	LUBS56-LCM	81648402841
LUBSCOV35-L	81648402812	LUBS56-RCM	81648402842
LUBSCOV45-L	81648402813	LUBS56-LBP	81648402843
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LUBSCOV56-L	81648402815		
LUBSCOV34-R	81648402816		
LUBSCOV35-R	81648402817		
LUBSCOV45-R	81648402818		
LUBSCOV46-R	81648402819		
LUBSCOV56-R	81648402820		
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LUBS35-LCM	81648402829		
LUBS35-RCM	81648402830		

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