

## Declaration of Conformity 2023-04 Headmaster Collar

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 : Truncal Orthoses 8 16484 99999-6**

PRODUCT IDENTIFICATION	
Product Name and Intended Purpose	Model Number (and UDI-DI)
<p><b>Headmaster Collar</b></p> <p>Intended Purpose: To provide support and control for the head</p> <p>Intended Users: Individuals requiring support and control of the head</p>	<p>AST01-B(81648400052), AST01-G(81648400049), AST01-K(81648400055),            AST01-U(81648400058), AST02-B (81648400053), AST02-G(81648400050),            AST02-K(81648400056), AST02-U(81648400059), AST03-B(81648400054),            AST03-G(81648400051), AST03-K(81648400057), AST03-U(81648400060),            HMC01-B(81648400007),HMC01-G (81648400001), HMC01-K(81648400013),            HMC01-U(81648400019), HMC02-B(81648400008), HMC02-G (81648400002),            HMC02-K(81648400014), HMC02-U(81648400020), HMC03-B(81648400009),            HMC03-G (81648400003), HMC03-K(81648400015), HMC03-U(81648400021),            HMC04-B(81648400010),HMC04-G (81648400004), HMC04-K (81648400016),            HMC04-U(81648400022), HMC05-B(81648400011), HMC05-G (81648400005),            HMC05-K(81648400017), HMC05-U(81648400023), HMC06-B(81648400012),            HMC06-G (81648400006), HMC06-K(81648400018), HMC06-U (81648400024),            HMCCS1-G(81648400061), HMCCS1-B(81648400065), HMCCS1-K(81648400069),            HMCCS1-U(81648400073), HMCCS2-B(81648400066),HMCCS2-G(81648400062),            HMCCS2-K(81648400070), HMCCS2-U (81648400074),            HMCCS3-B (81648400067),HMCCS3-G(81648400063), HMCCS3-K(81648400071),            HMCCS3-U (81648400075), HMCCS4-B(81648400068),HMCCS4-G(81648400064),            HMCCS4-K (81648400072), HMCCS4-U (81648400076 ), HMCNS01-B(81648400080),            HMCNS01-G (81648400077), HMCNS01-K(81648400083), HMCNS01-U (81648400086),            HMCNS03-B (81648400081), HMCNS03-G(81648400078), HMCNS03-K(81648400084),            HMCNS03-U (81648400087), HMCNS06-B(81648400082), HMCNS06-G(81648400079),            HMCNS06-K (81648400085), HMCNS06-U(81648400088), HMCPC-B(81648400045),            HMCPC-G (81648400042), HMCPC-K(81648400048), HMCPL-B (81648400043),            HMCPL-G (81648400040), HMCPL-K(81648400046), HMCPS-B (81648400044),            HMCPS-G (81648400041), HMCPS-K(81648400047), HMNPC-B (81648400036),            HMNPC-G (81648400033), HMNPC-K(81648400039), HMNPL-B (81648400034),            HMNPL-G (81648400031), HMNPL-K(81648400037), HMNPS-B (81648400035),            HMNPS-G (81648400032), HMNPS-K(81648400038)</p>
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: 2023-03-30

Manufacturer Name and Address: Symmetric Designs Ltd., 125 Knott Place, Salt Spring Island, B.C., V8K 2M4, Canada