

## Declaration of Conformity 2023-06 TOT

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 - 81648499999-6

PRODUCT IDENTIFICATION	
Product Name and Intended Purpose	Model Number (and UDI-DI)
TOT Collar Intended Purpose: To provide correction of Congenital Muscular Torticollis and Adult Idiopathic Torticollis. Intended Users: Individuals with Torticollis	TOT01 (81648400100), TOT02 (81648400101), CCOTJ (81648400102), CCETC (81648400103), CCOCS (81648400104), TOTPT (81648400105), CCTUB (81648400106)
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	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