

## Declaration of Conformity 2023-08 Apex Headrests

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)
<b>Apex Headrests</b>  To support the head of the occupant when seated in a wheelchair  Intended Users: Wheelchair users.	See attached Appendix I

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

AP200-U	81648400133	AP400-L	81648400570	140426	81648400656
AP250-U	81648400134	AP400-R	81648400571	140427	81648400657
AP300-U	81648400135	AP400S-K	81648400572	140428	81648400658
AP350-U	81648400136	AP400S-U	81648400573	140429	81648400659
APW230-U	81648400137	AP400S-P	81648400574	140470	81648400660
APW280-U	81648400138	AP400S-L	81648400575	140471	81648400661
AP200S-U	81648400142	AP400S-R	81648400576	140472	81648400662
AP250S-U	81648400143	AP450-K	81648400577	140473	81648400663
AP300S-U	81648400144	AP450-U	81648400578	140474	81648400664
AP350S-U	81648400145	AP450-P	81648400579	140475	81648400665
APW230S-U	81648400146	AP450-L	81648400580	140476	81648400666
APW280S-U	81648400147	AP450-R	81648400581	140477	81648400667
AP200-P	81648400193	AP450S-K	81648400582	140478	81648400668
AP250-P	81648400194	AP450S-U	81648400583	140479	81648400669
AP300-P	81648400195	AP450S-P	81648400584	140520	81648400670
AP350-P	81648400196	AP450S-L	81648400585	140521	81648400671
APW230-P	81648400197	AP450S-R	81648400586	140522	81648400672
APW280-P	81648400198	140220	81648400610	140523	81648400673
AP200S-P	81648400500	140221	81648400611	140524	81648400674
AP250S-P	81648400501	140222	81648400612	140525	81648400675
AP300S-P	81648400502	140223	81648400613	140526	81648400676
AP350S-P	81648400503	140224	81648400614	140527	81648400677
APW230S-P	81648400504	140225	81648400615	140528	81648400678
APW280S-P	81648400505	140226	81648400616	140529	81648400679
AP200-L	81648400506	140227	81648400617	140570	81648400680
AP250-L	81648400507	140228	81648400618	140571	81648400681
AP300-L	81648400508	140229	81648400619	140572	81648400682
AP350-L	81648400509	140270	81648400620	140573	81648400683
APW230-L	81648400510	140271	81648400621	140574	81648400684
APW280-L	81648400511	140272	81648400622	140575	81648400685

AP200S-L	81648400512	140273	81648400623	140576	81648400686
AP250S-L	81648400513	140274	81648400624	140577	81648400687
AP300S-L	81648400514	140275	81648400625	140578	81648400688
AP350S-L	81648400515	140276	81648400626	140579	81648400689
APW230S-L	81648400516	140277	81648400627		
APW280S-L	81648400517	140278	81648400628		
AP200-K	81648400518	140279	81648400629		
AP250-K	81648400519	140320	81648400630		
AP300-K	81648400520	140321	81648400631		
AP350-K	81648400521	140322	81648400632		
APW230-K	81648400522	140323	81648400633		
APW280-K	81648400523	140324	81648400634		
AP200S-K	81648400524	140325	81648400635		
AP250S-K	81648400525	140326	81648400636		
AP300S-K	81648400526	140327	81648400637		
AP350S-K	81648400527	140328	81648400638		
APW230S-K	81648400528	140329	81648400639		
APW280S-K	81648400529	140370	81648400640		
AP200-R	81648400530	140371	81648400641		
AP250-R	81648400531	140372	81648400642		
AP300-R	81648400532	140373	81648400643		
AP350-R	81648400533	140374	81648400644		
APW230-R	81648400534	140375	81648400645		
APW280-R	81648400535	140376	81648400646		
AP200S-R	81648400536	140377	81648400647		
AP250S-R	81648400537	140378	81648400648		
AP300S-R	81648400538	140379	81648400649		
AP350S-R	81648400539	140420	81648400650		
APW230S-R	81648400540	140421	81648400651		
APW280S-R	81648400541	140422	81648400652		
AP400-K	81648400567	140423	81648400653		
AP400-U	81648400568	140424	81648400654		
AP400-P	81648400569	140425	81648400655		