SWISS DECLARATION OF CONFORMITY

Medical Devices Ordinance (MedDO; SR 812.213)

Manufacturer: Convaid Products, LLC
2830 California St
Torrance, CA 90503
United States

SRN: US-MF-000002416

Swiss Authorized Representative (CH-REP)
Gelbart AG
Tribschenstrasse 64
6005 Luzern
Switzerland

CHRN: CHRN-AR-20001710

Declaration:

We, Convaid Products, LLC, declare under our sole responsibility that the medical devices identified in this Declaration conform to the applicable requirements of the Swiss Medical Devices Ordinance (MedDO; SR 812.213), including the applicable provisions of Regulation (EU) 2017/745 made applicable under the MedDO.

Device Identification:

Basic UDI-DI: 084011749SEATINGMWCVC
EMDN/GMDN: Y122103 / 41630
Device Description: Attendant-propelled wheelchair
Device Name: Cruiser
UDI-DI: See Appendix A

Intended Purpose:

The Convaid Cruiser is a manually operated mechanical wheelchair intended for medical purposes to provide seated mobility assistance to persons with mobility disabilities.

Risk Classification:

Class I, Rule 1, as defined in Annex VIII of Regulation (EU) 2017/745, as applicable under the MedDO.

Conformity Assessment Procedure:

Manufacturer's declaration of conformity for a Class I medical device in accordance with the applicable requirements of the MedDO and Regulation (EU) 2017/745.

Conformity Assessment Body: Not applicable
Certificate Number: Not applicable

Standards and/or Common Specifications:

See Appendix B

Authorization:

Place of Issue: Torrance, California, United States
Name: Gio Espinosa
Title: Director of QA/RA, North America Mobility
Date of Issue: 2026-10-28

Signature: 
Gio Espinosa
2026.10.28
12:51:12 -05'00'

For and on behalf of Convaid Products, LLC

Appendix A

Catalogue Number	Device Name	Variant	Device Description	UDI-DI
903314	Cruiser	10	Attendant-propelled wheelchair	00840117408005
904851	Cruiser	10	Attendant-propelled wheelchair with transit option	00840117408012
902845	Cruiser	12	Attendant-propelled wheelchair	00840117408029
904852	Cruiser	12	Attendant-propelled wheelchair with transit option	00840117408036
904532	Cruiser	12	Attendant-propelled wheelchair Scout package	00840117408043
905502	Cruiser	12	Attendant-propelled wheelchair with transit option and Scout package	00840117408050
900490	Cruiser	14	Attendant-propelled wheelchair	00840117408067
904853	Cruiser	14	Attendant-propelled wheelchair with transit option	00840117408074
905503	Cruiser	14	Attendant-propelled wheelchair with transit option and Scout package	00840117408081
904533	Cruiser	14	Attendant-propelled wheelchair Scout package	00840117408098
900145	Cruiser	16	Attendant-propelled wheelchair	00840117408104
904854	Cruiser	16	Attendant-propelled wheelchair with transit option	00840117408111
904534	Cruiser	16	Attendant-propelled wheelchair Scout package	00840117408128
905504	Cruiser	16	Attendant-propelled wheelchair with transit option and Scout package	00840117408135
902594	Cruiser	18	Attendant-propelled wheelchair	00840117408142
904855	Cruiser	18	Attendant-propelled wheelchair with transit option	00840117408159
904535	Cruiser	18	Attendant-propelled wheelchair Scout package	00840117408166
905505	Cruiser	18	Attendant-propelled wheelchair with transit option and Scout package	00840117408173

Appendix B

- EN ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- EN 12183:2022 Manual Wheelchairs – Requirements and test methods
- EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 14971:2019/A11:2021 Medical devices – Application of risk management to medical devices