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: Coaster
UDI-DI: See Appendix A

Intended Purpose:

The Convaid Coaster 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
12:46:43 -05'00'

For and on behalf of Convaid Products, LLC

Appendix A

Catalogue Number	Device Name	Variant	Device Description	UDI-DI
800121	Coaster	12	Attendant-propelled wheelchair	00840117408425
800123	Coaster	12	Attendant-propelled wheelchair Scout package	00840117408432
800122	Coaster	12	Attendant-propelled wheelchair with transit option	00840117408449
800124	Coaster	12	Attendant-propelled wheelchair with transit option and Scout package	00840117408456
800141	Coaster	14	Attendant-propelled wheelchair	00840117408463
800143	Coaster	14	Attendant-propelled wheelchair Scout package	00840117408470
800142	Coaster	14	Attendant-propelled wheelchair with transit option	00840117408487
800144	Coaster	14	Attendant-propelled wheelchair with transit option and Scout package	00840117408494
800161	Coaster	16	Attendant-propelled wheelchair	00840117408500
800163	Coaster	16	Attendant-propelled wheelchair Scout package	00840117408517
800162	Coaster	16	Attendant-propelled wheelchair with transit option	00840117408524
800164	Coaster	16	Attendant-propelled wheelchair with transit option and Scout package	00840117408531
800181	Coaster	18	Attendant-propelled wheelchair	00840117408548
800183	Coaster	18	Attendant-propelled wheelchair Scout package	00840117408555
800182	Coaster	18	Attendant-propelled wheelchair with transit option	00840117408562
800184	Coaster	18	Attendant-propelled wheelchair with transit option and Scout package	00840117408579

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