



EU Declaration of Conformity

**Manufacturer
Manufacturer Address:**

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SRN

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**EU Authorized
Representative/SRN**

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Statement

We, Convoid Products, LLC, hereby declare, under our sole responsibility, that the medical device(s) specified below complies with the relevant the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and their relevant transposition into national laws of the Member States in which the below-mentioned device(s) are distributed. for medical devices.

Basic UDI-DI

084011749SEATINGMWCVC

EMDN/GMDN

Y122103 / 41630

Device description

Attendant propelled wheelchair

Device name(s)

Coaster

Intended Purpose

The Convoid Coaster ensures mobility in outdoor areas when transport is required on a regular basis. Rehab wagons are used for the transport of children and adolescents with disabilities.

UDI-DI

See appendix A

Risk class of the device

Class I, Rule I as defined in annex VIII

Conformity Assessment Route

Annex II and III

**Harmonized Standards/Common
Specification**

See appendix B

**Date of Issue
Name and function**

February 3, 2026
Mark Murphy, QA/RA Manager/PRRC



Signature, on behalf of Convoid 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