



EU Declaration of Conformity

Manufacturer
Manufacturer Address:

Convoid Products, LLC
2830 California St, Torrance, CA 90503
United States
18448766245
www.etac.com

SRN

US-MF-000002416

**EU Authorized
Representative/SRN**

R82 A/S
Parallelsvej 3.8751 Gedved, Denmark
DK-AR-000001289

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

08401174900052

EMDN/GMDN

Y122103 / 41630

Device description

Attendant propelled wheelchair

Device name(s)

Coaster

Intended Purpose

The Convoid Coaster is an attendant-propelled device. Its intended function and use is to assist a disabled person in performing an activity that the person would otherwise find difficult to do or be unable to do such as said person from one place to another while sitting. The chair is intended to always be under the control and supervision of an attendant, and the occupant should never be left unattended.

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

August 25, 2025

Name and function

Mark Murphy, QA/RA Manager/PRRC

Mark Murphy

Signature, on behalf of Convoid Products, LLC

Appendix A

Catalogue Number	Device Name	Variant	Device Description	UDI-DI
800121	Coaster	12	Attendant propelled wheelchair	00840117400808
800123	Coaster	12	Attendant propelled wheelchair Scout package	00840117400822
800122	Coaster	12	Attendant propelled wheelchair with transit option	00840117400815
800124	Coaster	12	Attendant propelled wheelchair with transit option and Scout package	00840117400839
800141	Coaster	14	Attendant propelled wheelchair	00840117400846
800143	Coaster	14	Attendant propelled wheelchair Scout package	00840117400860
800142	Coaster	14	Attendant propelled wheelchair with transit option	00840117400853
800144	Coaster	14	Attendant propelled wheelchair with transit option and Scout package	00840117400877
800161	Coaster	16	Attendant propelled wheelchair	00840117400884
800163	Coaster	16	Attendant propelled wheelchair Scout package	00840117400907
800162	Coaster	16	Attendant propelled wheelchair with transit option	00840117400891
800164	Coaster	16	Attendant propelled wheelchair with transit option and Scout package	00840117400914
800181	Coaster	18	Attendant propelled wheelchair	00840117400921
800183	Coaster	18	Attendant propelled wheelchair Scout package	00840117400945
800182	Coaster	18	Attendant propelled wheelchair with transit option	00840117400938
800184	Coaster	18	Attendant propelled wheelchair with transit option and Scout package	00840117400952

Appendix B

EN ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)

EN 12183:2009 Manual Wheelchairs – Requirements and test methods

EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016)

EN ISO 14971:2012 Medical devices – Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)