



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)

Rodeo

Intended Purpose

The Convoid Rodeo is an attendant-propelled device. Its intended function and use is to provide mobility to children to adults suffering from congenital or traumatic brain damage, degenerative or other physical handicaps that result in the lack of coordination or control, muscle weakness or paralysis.

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**

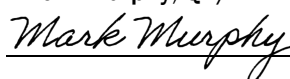
See appendix B

Date of Issue

August 21, 2025

Name and function

Mark Murphy, QA/RA Manager/PRRC



Signature, on behalf of Convoid Products, LLC

Appendix A

Catalogue Number	Device Name	Variant	Device Description	UDI-DI
904340	Rodeo	10	Attendant propelled wheelchair	10840117403311
904860	Rodeo	10	Attendant propelled wheelchair with transit option	10840117405803
904971	Rodeo	10	Attendant propelled wheelchair without seating	10840117400228
904967	Rodeo	10	Attendant propelled wheelchair with transit option, without seating	10840117400235
902689	Rodeo	12	Attendant propelled wheelchair	10840117401478
904861	Rodeo	12	Attendant propelled wheelchair with transit option	10840117405810
904972	Rodeo	12	Attendant propelled wheelchair without seating	10840117400242
904968	Rodeo	12	Attendant propelled wheelchair with transit option, without seating	10840117400259
902691	Rodeo	14	Attendant propelled wheelchair	10840117401485
904862	Rodeo	14	Attendant propelled wheelchair with transit option	10840117405827
904973	Rodeo	14	Attendant propelled wheelchair without seating	10840117400266
904969	Rodeo	14	Attendant propelled wheelchair with transit option, without seating	10840117400273
903134	Rodeo	16	Attendant propelled wheelchair	10840117401751
904863	Rodeo	16	Attendant propelled wheelchair with transit option	10840117405834
904974	Rodeo	16	Attendant propelled wheelchair without seating	10840117400303
904970	Rodeo	16	Attendant propelled wheelchair with transit option, without seating	10840117400310

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)