



EU Declaration of Conformity

Manufacturer Convaid Products, LLC

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EU Authorized R82 A/S

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DK-AR-000001289

Statement We, Convaid 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) Cruiser

Intended Purpose The Convaid Cruiser 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 Convaid Products, LLC



Appendix A

Catalogue Number	Device Name	Variant	Device Description	UDI-DI
903314	Cruiser	10	Attendant propelled wheelchair	10840117401959
904851	Cruiser	10	Attendant propelled wheelchair with transit option	10840117405711
902845	Cruiser	12	Attendant propelled wheelchair	10840117401492
904852	Cruiser	12	Attendant propelled wheelchair with transit option	10840117405728
904532	Cruiser	12	Attendant propelled wheelchair Scout package	10840117400013
905502	Cruiser	12	Attendant propelled wheelchair with transit option and Scout package	10840117400037
900490	Cruiser	14	Attendant propelled wheelchair	10840117400341
904853	Cruiser	14	Attendant propelled wheelchair with transit option	10840117405735
905503	Cruiser	14	Attendant propelled wheelchair with transit option and Scout package	10840117400075
904533	Cruiser	14	Attendant propelled wheelchair Scout package	10840117400044
900145	Cruiser	16	Attendant propelled wheelchair	10840117400068
904854	Cruiser	16	Attendant propelled wheelchair with transit option	10840117405742
904534	Cruiser	16	Attendant propelled wheelchair Scout package	10840117400082
905504	Cruiser	16	Attendant propelled wheelchair with transit option and Scout package	10840117400099
902594	Cruiser	18	Attendant propelled wheelchair	10840117401249
904855	Cruiser	18	Attendant propelled wheelchair with transit option	10840117405759
904535	Cruiser	18	Attendant propelled wheelchair Scout package	10840117400105
905505	Cruiser	18	Attendant propelled wheelchair with transit option and Scout package	10840117400129



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)