Declaration of Conformity

for PDG Manual Wheelchairs

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices.

The undersigned declares that the products described in this document meet the Council provisions that apply to them, and that the CE Mark may be affixed.

General Product Name:	PDG Manual Wheelchairs
Legal Manufacturer: (Name on Label)	PDG Product Design Group Inc. (PDG Mobility) 318 East Kent Avenue South Vancouver BC V5X 4N6 CANADA
SRN:	CA-MF-000009801
Basic UDI-DI:	++B829PDGWHEELCHAIRB7
Variants:	As per Appendix II (in this document) – Product Listing/Schedule
Intended Purpose:	Highly adjustable mobility aids for specified patient groups as described in the appropriate instructions for use for each design.
MDR Classification:	Class I [Rule I]
Notified Body:	Not Applicable for Class I
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Directive Assessment Route:	Conformity assessment based on EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III.
Device Registration Ref:	MT-MDF03-AA239A

Name Thomas Dietsch **Position** President

Signed **Date** February 10, 2022 Vancouver, Canada

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/745/EU	EU Medical Device Regulation 2017/745
EN ISO 14971:2012	Medical devices -- Application of risk management to medical devices
EN ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009	Biological evaluation of medical devices Part 1: Evaluation and testing
MEDDEV 2.12-1 rev 8, December 2013	Guidelines on a Medical Device Vigilance System.
MEDDEV 2.7/1: rev. 4, June 2016	Clinical evaluation: A guide for manufacturers and notified bodies.
ISO 7176-1:1999/2014	Determination of static stability
ISO 7176-3:2003/2012	Determination of effectiveness of brakes
ISO 7176-5:2008/2014	Determination of dimensions, mass, and manoeuvring space
ISO 7176-7:1998	Measurement of seating and wheel dimensions
ISO 7176-8:1998/2014	Requirements and test methods for static, impact and fatigue strengths
ISO 7176-13:1989	Determination of coefficient of friction of test surfaces
ISO 7176-15:1996	Requirements for information disclosure, documentation, and labelling
ISO 7176-22:2000/2014	Set-up procedures

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code	UDI-DI
5510	Bentley	41620	B829101
5511	Eclipse	38803	B829111
5512	Stellar	41620	B829121
5515	Fuze T50	41620	B829151
5516	Fuze T20	41620	B829161
5517	Fuze JR	41620	B829171
5519	Stellar GL	41620	B829191
5520	Elevation	41620	B829201
5521	Stellar HD	38803	B829211
5522	Stellar LEAP	41620	B829221
5523	Stellar Impact	41620	B829231
5524	Bentley LT	41620	B829241
5525	Stellar GLT	41620	B829251
5526	Fuze T50n	41620	B829261
5527	Bentley LT-R	41624	B829271

Version History

Version	Compiled by	Date	Description
1.0	Thomas Dietsch	April 9, 2019	First issue
2.0	Anna Galluzzo	March 24, 2020	Second issue
3.0	Thomas Dietsch	July 15, 2020	Added Fuze T50n
4.0	Thomas Dietsch	March 1, 2021	Added Advena SRN and PDG Basic UDI-DI
5.0	Thomas Dietsch	July 14, 2021	Added PDG SRN
6.0	Thomas Dietsch	February 10, 2022	Added Bentley LT-R

Certificate of Designation

Eudamed Mandate Summary

Client Ref.	**CAN/2001/05/03**	**Date of Issue:** 5 February 2024
Issued To:	**PDG Product Design Group Inc (PDG Mobility)** Unit 103-318 East Kent Avenue South Vancouver BC V5X 4N6 Canada	**Legal Manufacturer [SRN: CA-MF-000009801]**
Issued By:	**Advena Limited** Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013. Malta.	**EC-REP [SRN: MT-AR-000000234]**
EU Competent Authority:	**Malta Medicines Authority (MMA)** Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000 Malta. Tel: +356 2343 9000 Email: info.medicinesauthority@gov.mt	**Eudamed Actor ID: MT-CA-019**

In accordance with the Mandate executed by both the Legal Manufacturer and Advena Limited, this Certificate of Designation is issued and confirms the period of representation. Furthermore, this certificate confirms the medical devices Advena Limited acts as EU Authorised Representative for the Legal Manufacturer.

This certificate alone does not provide confirmation that the devices listed in Appendix A can be legitimately placed on the market. The Legal Manufacturer must be able to provide satisfactory regulatory evidence that the devices mentioned in Appendix A meet with the requirements of the applicable legislation and have the applicable valid certifications.

The devices listed in Appendix A must indicate Advena Ltd as the EU Authorised Representative, and in the following format, as applicable to EU legislation:

EC	REP

Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Anthony Kirby – Managing Director

AR Cover Begins: 01 February 2024 **AR Cover Ends:** 31 January 2025

[MDR/IVDR] **Mandate Start:** 13 January 2023 **Mandate End:** N/A **Mandated for Vigilance:** No

This certificate is subject to the organisation maintaining their documentation in compliance with the EU legislation as indicated in this certificate.

This certificate is for the exclusive use of Advena Ltd's clients and is provided pursuant of the European Authorised Representative agreement (Mandate) between Advena Ltd and the client. Advena's responsibility and liability is limited to the terms and conditions of this agreement. Advena Ltd assumes no liability to any party for any loss, expense or damage occasioned by the use of this certificate and the European Authorised Representative agreement (Mandate). Only the client is authorised to copy or distribute this certificate. Any use of the Advena Ltd name by others who are not covered by the above agreement, or any similar contract, is prohibited. This certificate remains valid until the expiry date has been reached or has been terminated by Advena Limited.

Appendix A

Table 1: List of devices (generic device group(s)) covered within the executed Mandate (authorised representative list).

Product Details, Names or Trade Names	EU Legislation	Classification	Date of Declaration
PDG Manual Wheelchairs	MDR	Class I	14/07/2021

Certificate of Registration

Client Ref. **CAN/2001/05/03**

Issued To: **PDG Product Design Group Inc (PDG Mobility)**
318 East Kent Avenue South,
Vancouver, BC
V5X 4N6
Canada

Legal Manufacturer [SRN: CA-MF-000009801]

Issued By: **Advena Limited**
Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013. Malta.

EC-REP [SRN: MT-AR-000000234]

EU Competent Authority: **Malta Medicines Authority (MMA)**
Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000
Malta.
Tel: +356 2343 9000
Email: info.medicinesauthority@gov.mt

Eudamed Actor ID: MT-CA-019

We hereby declare that:

- Device registrations for the medical devices mentioned within this certificate have duly been completed with the Malta Medicines Authority (MMA) the Competent Authority of Malta.
- Due to the 26th May 2021 Date of Application of Regulation (EU) 2017/745 (MDR) the validity of this certificate is subject to the Legal Manufacturer providing satisfactory evidence that any device claiming compliance to Directive 93/42/EEC (MDD) through Article 120 (3) of Regulation (EU) 2017/745 as amended, is legitimately permitted.
- Due to the 26th May 2022 Date of Application of Regulation (EU) 2017/746 (IVDR) the validity of this certificate is subject to the Legal Manufacturer providing satisfactory evidence that any device claiming compliance to Directive 98/79/EC (IVDD) through Article 110(3) of Regulation (EU) 2017/746 as amended, is legitimately permitted.

Anthony Kirby – Managing Director

Date of Issue: 5 February 2024 **AR Cover Begins:** 01 February 2024 **AR Cover Ends:** 31 January 2025

This certificate is subject to the organisation maintaining their documentation in compliance with the EU legislation as indicated in this certificate.

This certificate is for the exclusive use of Advena Ltd's clients and is provided pursuant of the European Authorised Representative agreement (Mandate) between Advena Ltd and the client. Advena's responsibility and liability is limited to the terms and conditions of this agreement. Advena Ltd assumes no liability to any party for any loss, expense or damage occasioned by the use of this certificate and the European Authorised Representative agreement (Mandate). Only the client is authorised to copy or distribute this certificate. Any use of the Advena Ltd name by others who are not covered by the above agreement, or any similar contract, is prohibited. This certificate remains valid until the expiry date has been reached or has been terminated by Advena Limited.

Appendix A

Product Details, Names or Trade Names	EU Legislation	Classification	Device Registration Reference(s)
PDG Manual Wheelchairs	MDR	Class I	MT-MDF03-AA239A