Certificate of Registration

In accordance with European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

Certificate No.
CAN/2001/05/03

Certificate issue date;
11th April 2019

Certificate expiry date;
31st January 2020

We hereby declare that

- **An examination has been made of this organisation's Declaration of Conformity(s) and where appropriate Notified Body certification(s) exist.**
- **The EU Authorised Representative contract has been fulfilled**

And the CE mark may be applied to the products listed below.

Organisation / Client:

PDG Product Design Group Inc (PDG Mobility)
#103-318 East Kent Avenue South
Vancouver
BC V5X 4N6
Canada

Products:

PDG Manual Wheelchairs

Competent Authority Information:

Class I Medical Device Directive registration is with the Malta Competition and Consumer Affairs Authority (MCCAA) and the below registration has been issued.

DVC-MT-19-04-000145

Authorised Representative Labelling Information:

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

Advena Limited.

Registered office;
Tower Business Centre, 2nd Flr, Tower Street,
Swatar, BKR 4013. Malta
Registered in Malta No. C 76865

☎ +44 1926 800153
Email; info@advenamedical.com

Authorised Signature:

This certificate is subject to the organisation maintaining their documentation in compliance with the regulations stated in this certificate.

Declaration of Conformity

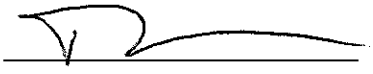
for PDG Manual Wheelchairs

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and 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
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	Highly adjustable mobility aids for specified patient groups as described in the appropriate instructions for use for each design.
MD Directive Classification:	Class I
Notified Body:	Not Applicable for Class I
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Medical Device Directive Assessment Route:	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

Name Thomas Dietsch **Position** President

Signed  **Date** April 9, 2019

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:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
	Wheelchairs:
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
5515	Fuze T50	41620
5516	Fuze T20	41620
5517	Fuze JR	41620
5510	Bentley	41620
5524	Bentley LT	41620
5512	Stellar	41620
5519	Stellar GL	41620
5525	Stellar GLT	41620
5521	Stellar LEAP	41620
5522	Stellar HD	38803
5523	Stellar Impact	41620
5511	Eclipse	38803
5520	Elevation	41620

Version History

Version	Compiled by	Date	Description
1.0	Thomas Dietsch	April 9, 2019	First issue