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 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:	TBD
Basic UDI-DI:	As per Appendix II (in this document) – Product Listing/Schedule PDG is registered with HIBCC under company number B829.
Variants:	As per Appendix II (in 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 [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:	TBD
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.

Name Thomas Dietsch **Position** President

Signed  **Date** March 10, 2020 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
ISO 13485:2016	Medical devices – Quality management systems – System requirements for regulatory purposes.
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
5515	Fuze T50	41620	B829151
5516	Fuze T20	41620	B829161
5517	Fuze JR	41620	B829171
5510	Bentley	41620	B829101
5524	Bentley LT	41620	B829241
5512	Stellar	41620	B829111
5519	Stellar GL	41620	B829191
5525	Stellar GLT	41620	B829251
5522	Stellar LEAP	41620	B829221
5521	Stellar HD	38803	B829211
5523	Stellar Impact	41620	B829231
5511	Eclipse	38803	B829111
5520	Elevation	41620	B829201

Version History

Version	Compiled by	Date	Description
1.0	Thomas Dietsch	April 9, 2019	First issue
2.0	Anna Galluzzo	March 6, 2020	Second issue