
	Document No.	DC-04	Issue No.	6.0	Page	1 of 2
	Prepared By	John Adcock		Date	March 2018	
DECLARATION OF CONFORMITY European Communities Council Directives 93/42/EEC and 2007/42/EC Concerning Medical Devices Manual Wheelchairs						

Date	Issue No.	Compiled by	Amendment Description
17 th February 2012	1.0	John Adcock	New document; Replaces earlier declarations that related to specific products.
11 th August 2014	2.0	James Formby	Change of EU Authorised Representative Address
18 th November 2014	3.0	Nalini McIntosh	Add Stellar GL and Elevation to Annex A:Product Variations
7 th September 2015	4.0	John Adcock	Correction of AS (applicable standards) reference, was AS 101, now AS-04
21 st January 2016	5.0	Louis Belanger	Correction of previous Issue No.'s and update to Annex A Product Variations to add Elevation and Stellar GL as per DC-04 Issue No. 3.0
27 th March 2018	6.0	Neil McKinnon	Added Stellar Leap and Stellar Impact to Annex A: Product Variations.

The undersigned declares that the medical devices described below meet the provisions of the Council Directives which apply and the CE Mark may therefore be affixed. The Products are registered with the UK Competent Authority. All supporting documentation is retained at the premises of the manufacturer.

Product Description	Manual wheelchairs as, manufactured by this company, see Annex A
Manufacturer	PDG - Product Design Group, Unit 103-318 East Kent Ave. South, Vancouver, BC, Canada V5X 4N6
Intended Use	Highly adjustable mobility aids for specified patient groups as described in the appropriate instructions for use for each design.
MDD Classification	Class I (one) - Annex IX, Rule 1
Notified Body	Not applicable
EU Authorised Representative	Advena Ltd. Registered office; Pure Offices, Plato Close Tachbrook Park, Warwick, CV34 6WE, UK
Assessment route	Self certification by Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.
Applicable product standards.	As shown in document AS-04

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Signed



Date March 27th, 2018

Name (printed)

Neil McKinnon

Position

Quality Manager

ANNEX A

Product Variations;

- Elevation
- Eclipse
- Bentley
- Stellar
- Stellar GL
- Stellar Leap
- Stellar Impact
- Fuze T50
- Fuze T20
- Fuze JR

This declaration covered spares and accessories made available to these wheelchairs.