

Title	DECLARATION OF CONFORMITY – Astrotilt & Fuze Wheelchairs.		DC - 03 issue 2
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**PDG - Product Design Group.**  
**Declaration of Conformity for Astrotilt and Fuze Wheelchairs**

Version	Compiled by	Date	Description
A	John Adcock	Feb 1, 2006	First issue
2	John Adcock	June 15, 2007	Fuze wheelchair added.

**European Communities Council Directive 93/42/EEC**  
**Concerning Medical Devices**

as transposed into UK national law by the Medical Device Regulations 1994 (S.I 1994/3017 Consumer Protection). Amended by the Active Implantable Medical Device Regulations 1995 (S.I 1995/1671).

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:** Astrotilt and Fuze tilt-in-space wheelchairs.

**Manufacturer:** PDG - Product Design Group  
Unit 102 - 366 East Kent Ave. South Vancouver, BC, Canada V5X 4N6.

**Variants;** Astrotilt (Adult and geriatric)  
Astrotilt junior. (Child or small adult).  
Fuze T 50  
Fuze T20

**Intended Use:** As defined in the Product Summary and Classification Rational Document CLR-03

**Sterile:** No


**Measuring Function:** No

**Conforming to Product Standards:** EN 1041; 1998. Information supplied by the manufacturer with medical devices  
BS EN ISO 14971-2001 Medical devices - Application of risk management to medical devices.  
ANSI/RESNA WC19 (Crash testing and tie-down systems.)  
AS 3695 and 3696 (Equivalent to ISO 7176 parts 1, 3, 5, 7, 8 and 15).  
Flammability performance standards -  
- California Technical Bulletin 117, Sec. A, Part I  
- California Technical Bulletin 117, Sec. D, Part II  
- US Federal M.V.S.S. 302

**MDD Directive Classification No:** 1 (One)

**Notified Body;** None, not applicable for Class 1 devices that are not sterile or have no measuring function.

**Medical Device Directive Assessment route:** Self certification by Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

Signed  Date June 15/07

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 the PDG - Product Design Group name, regardless of whether these operations are carried out by the manufacturer, or on his behalf by a third party.

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**Statement**

This document is the PDG - Product Design Group statement on the conformance of these medical devices to European Council Directive 93/42/EEC dated 14 June 1993 Annex VII paragraphs 3, 4 and 5 in reference to the application of an EC Declaration of Conformity.

3) *The technical documentation must allow assessment of the conformity of the product with the requirements of the Directive. It must include in particular:*

- *a general description of the product, including any variants planned;*

a) See page 1 of this Declaration, the Classification Rational Document, other technical information in the Technical File, plus additional documentation maintained by PDG - Product Design Group, and/or their subcontractors. All variants are covered by this document.

- *design drawings, methods of manufacture envisaged and diagrams of components, subassemblies, circuits, etc.;*

b) Drawings, manufacturing and other specifications are filed with PDG - Product Design Group, and/or their subcontractors, as controlled documents.

- *the descriptions and explanations necessary to understand the above mentioned drawings and diagrams and the operations of the product;*

c) Product manufacturing instructions, product user instructions, drawings and specifications are filed with PDG - Product Design Group, and/or their subcontractors. Instructions for use, including applicable technical information, are available for each device.

- *the results of the risk analysis and a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if the standards referred to in Article 5 have not been applied in full.*

d) The risk analysis, and the essential requirement check list, is referenced in the Technical File. General requirements for safety have been covered by testing to the standards referenced on page 1 of this document.

- *in the case of products placed on the market in a sterile condition, description of the methods used.*

e) Not applicable

- *the results of the design calculations and of the inspections carried out, etc.; if the device is to be connected to other devices(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer;*

f) This device is not intended to be connected to any other medical product. .

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*-the test reports and, where appropriate, clinical data in accordance with Annex X;*

- g) This device has similarity to other wheelchairs and mobility aids manufactured by this company and formal clinical evaluations are not considered necessary over and above the extensive design validations that have been carried out.

*- the label and instructions for use;*

- h) As shown in the Technical File.

4) *The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relating to the product. He shall notify the competent authorities of the following incidents immediately on learning of them:*

- i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;*
- ii) any technical or medical reason connected with the characteristics on the performance of a device for the reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.*

- i) PDG - Product Design Group maintain procedures for post market surveillance, device vigilance and the prompt handling, processing and analysis of customer complaints. Any technical reports, customer comments or dissatisfaction reports will be returned promptly to the manufacturer, either directly or via a representative or distributor, for review, comment and for any applicable device reporting and corrective or preventative actions.

*With products placed on the market in sterile condition and Class I devices with a measuring function, the manufacturer must observe not only the provisions laid down in this Annex but also one of the procedures referred to in Annex IV, V or VI. Application of the above mentioned Annexes and the intervention by the notified body is limited to:*

- in the case of products placed on the market in sterile condition, only the aspects of manufacture concerned with securing and maintaining sterile conditions;*
- in the case of devices with a measuring function, only the aspects of manufacture concerned with the conformity of the products with the metrological requirements.*

- j) Not applicable to these products.