

PDG Product Design Group Inc.

9165 Shaughnessy Street
Vancouver BC
Canada V6P 6R9

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

DECLARATION OF CONFORMITY Certificate No: DC-1

The undersigned declares that the products named and listed on this certificate meet the provisions of this Council Directive which apply to them and the CE Mark may be affixed.

General Product Name: Manual Wheelchairs

Labelled Manufacturer: PDG Product Design Group Inc.
9165 Shaughnessy Street
Vancouver BC
Canada V6P 6R9

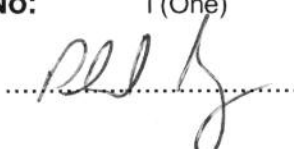
Intended Use: Mobility aid for the disabled.

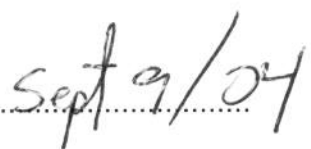
Sterile: No

Measuring Function: No

Conforming to Product Standards: ISO 7176 load testing

Directive Classification No: I (One)

Signed (manufacturer): 

Date: 

Name: Phil. Mundy,

Position: President

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 his own name, regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

DECLARATION OF CONFORMITY - continued.

Products covered by this certificate:

Name	Description
Eclipse 350	Manually operated wheelchair
Eclipse 600	Manually operated wheelchair
Bentley	Manually operated wheelchair
Stellar	Manually operated wheelchair

Statement

This document is the PDG Product Design Group Inc. statement on the conformance of the products listed in this Certificate as to their conformity 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 pages 2 of this document

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

b) See product specifications and drawings which are located at the facility of PDG Product Design Group Inc., 9165 Shaughnessy Street, Vancouver BC, Canada V6P 6R9, and/or their subcontractors which are defined by purchase order and contract.

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

c) A user guide is supplied with the devices. Other information, including work instructions and product assembly instructions are on file with the manufacturer, PDG Product Design Group Inc., 9165 Shaughnessy Street, Vancouver BC, Canada V6P 6R9, and/or their subcontractors which are defined by purchase order and contract.

- *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) These products do not conform to any European harmonised standards. Conformance to the essential requirements is described, and a risk analysis given, see accompanying documents.

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

e) Not applicable to these devices

- *the results of the design calculations and of the inspections carried out, etc.; if the device is to be connected to other device(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) These devices are not intended to be connected to any other device.

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

- g) Similar devices have been on the market for many years and have had no formal clinical investigation reports. PDG Product Design Group Inc. have an extensive internal safety testing program to assure safety and efficacy and also the company has a regulated and controlled vigilance and customer complaint procedure that ensures that any problems found in the use of the devices will be subjected to corrective action.

- the label and instructions for use;

- h) Texts and typical samples of labels and instructions for use are given in this 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 Inc. have a regulated and controlled vigilance and customer complaint procedure that ensures that any problems found in the use of the devices are subjected to corrective action. The analysis of such complaints is maintained at the manufacturing facility.

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.