Motion Concepts Declaration of Conformity for Seat Cushions and Accessories

Revision	Compiled by	Date	Description
1	John Adcock	October 18, 2006	New document
2	Paul Patten	September 27, 2010	Added Annex A
3	Paul Patten	January 6, 2011	Updates to Standards and technical file (TF-01)
4	Paul Patten	April 18,2011	Updates for IVC-Matrx Seating Series
5	Paul Patten	January 26,2012	Updates to Annex A (metric codes)
6	P. Patten	February 4, 2013	Updates to Annex A (HD Matrx-Vi Cushions)
7	P. Patten	August 5, 2014	Updated EU REP address
A	P. Patten	November 13, 2015	Updates to Annex A (remove Non-IVC models)

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

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:	Invacare-Matrx Seating Series *(Matrx-Vi, Kidabra-Vi, Matrx PS)* Cushions and Accessories.
Manufacturer:	Motion Concepts Canada, 84 Citation Drive, Units 1-3, Concord, Ontario, Canada L4K 3C1
Variants;	Refer to Annex A– Product and Accessory List: Invacare-Matrx Seat Cushions- TRD0423-Rev A (Technical File TF-01)
Intended Use:	Anatomically designed moulded seat cushions offering pressure reduction comfort and positioning for users at moderate to high risk of skin breakdown. The cushions are primarily designed as accessories for wheelchair users but may have other seating applications.
Sterile:	No
Measuring Function:	No
Conforming to Product Standards:	EN 12182-1999 Technical aids for disabled persons- General requirements and Test Methods EN 980-2003 Graphical symbols for use with medical devices. EN 1041-1998. Information supplied by the manufacturer with medical devices. BS EN ISO 14971-2009 Medical Devices - Application of risk management to medical devices. EN1021-1/-2-2006: Testing of ignitability for upholstered furniture EN 10993-5-2009: Biological evaluation of medical devices (Part 5: Tests for in-vitro cytotoxicity)
MDD Directive Classification No:	1 (one)
Notified Body;	None, not applicable for Class 1 devices that are not sterile or have no measuring function.
European Authorised Representative;	Advena Ltd, Pure Offices, Plato Close, Warwick, CV34 6WE, UK
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 J Rowley **Judy Rowley** (Director of Global Product Mgmt) **Date** 13-NOV-2015

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the devices are placed on the market under the Motion Concepts name, regardless of whether these operations are carried out by the manufacturer or on his/her behalf by a third party.

Statement

This document is the Motion Concepts 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 Product Description and Classification Rational Document CLR 01, the product and accessory list shown in the Technical File, plus additional documentation maintained by Motion Concepts and/or their subcontractors. All variants are covered by this Declaration.

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

b) Drawings, manufacturing and other specifications are filed with Motion Concepts 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 Motion Concepts and/or their subcontractors. Instructions for use, including applicable technical information, are available.

- 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) A risk management study, and an essential requirement check list, are provided in the Technical File TF 01 and refer to applicable standards. General requirements for safety have been covered by product testing.

- 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) These devices are intended to be normally connected directly to a wheelchair, or other mobility aid for the disabled, and this has been considered when preparing the risk management study and the essential requirement check list.

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

g) These devices have been manufactured by Motion Concepts and sold in the US and Canada for several years but without formal clinical evaluations as these were not required by local regulation. However, safety and user tests were performed (as listed in the technical file, including pressure mapping studies and some ergonomic reviews) and the company is pro-active in addressing post-market reports so as to assure continual design improvement.

- *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) Motion Concepts 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.