Motion Concepts Declaration of Conformity for Invacare-Matrx Back Cushions and Accessories

EC Council MDD 93/42/EEC and Directive 2007/47/EC 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, Back Cushions and Accessories
Manufacturer:	Motion Concepts Canada, 84 Citation Drive, Units 1-9, Concord, Ontario, Canada L4K 3C1
Variants;	Refer to Annex A– Product and Accessory List: Invacare-Matrx Back Cushions- TRD0425-Rev C (Technical File TF-02)
Intended Use:	Back cushions are primarily designed as accessories to provide stability, comfort and positioning for wheelchair users, but may have other seating applications.
Sterile:	No
Measuring Function:	No
Conforming to Product Standards:	EN 12182:2012, Assistive products for persons with disability. General requirements and test methods EN 12183:2014, Manual wheelchairs-Requirements and test methods EN 980:2008 Graphical symbols for use with medical devices. EN 1041:2008. Information supplied by the manufacturer with medical devices. EN ISO 14971:2012 Medical Devices - Application of risk management to medical devices. EN1021-1/-2:2014 Testing of ignitability for upholstered furniture or ISO 8191-1:1987 Furniture -- Assessment of the ignitability of upholstered furniture -- Part 1: Ignition source: smouldering cigarette, and ISO 8191-2:1988 Furniture -- Assessment of the ignitability of upholstered furniture -- Part 2: Ignition source: match-flame equivalent EN 10993-5:2009: Biological evaluation of medical devices (Part 5: Tests for in-vitro cytotoxicity)
MDD Classification No:	Class 1 (one)
Notified Body;	None, not applicable for Class 1 devices that are not sterile or have no measuring function.
EU 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** 12-OCT-2018

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 and its intended use(s);

a) See page 1 of this Declaration, the Product Description and Classification Rational Document CLR 02, 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 02 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 and the validation report;

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 and this has been considered when preparing the risk management study and the essential requirement check list.

- the solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art; and as appropriate, pre-clinical evaluation and clinical evaluation 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 have been performed (as listed in the technical file) 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, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product. The Manufacturer 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 II, 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.

REVISION SUMMARY:

Rev	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 7, 2011	Updates to Standards and technical file (TF-02)
4	Paul Patten	April 8, 2011	Updated Annex A
5	Paul Patten	December 7, 2011	Updated Annex A (metric codes)
6	Paul Patten	January 26, 2012	Updates to Annex A
7	P. Patten	February 1, 2013	Updates to Annex A
8	P. Patten	August 5, 2014	Updated EU REP address
9	P. Patten	October 8, 2014	Updated Annex A –added new Elite TR sizes
A	P. Patten	November 3, 2015	Updated Annex A- added PBE-HD-TR and EDB-HD, removed Matrx Genera Back & PBE-FB
B	P. Patten	October 17, 2016	Updated Annex A- added MINI Back and Elan headrest/hardware; removed MX1 SuperLite
C	P. Patten	September 5, 2017	Updated Annex A- added MX2 Back models; corrected table to indicate EN 12182:2012 standard
D	P. Patten	October 9, 2018	Correction to Product Standards: updated to indicate EN 980:2008; EN 1041:2008 and EN 1021-1-2:2014, added reference to EN 12183:2014 standard and ISO 8191-1/-2; moved revision summary to the end of the DoC