

	Document ID : TRD0548 Rev B	
	Date: 31-Aug-2020	
MTDC-02	EU Declaration of Conformity	Page 1 of 2

Declaration of Conformity for Invacare-Matrix Seating Series, Back Supports and Accessories

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

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-Matrix Seating Series, Back Supports and Accessories.
Legal Manufacturer:	Motion Concepts, 84 Citation Drive, Units 1-9, Concord, Ontario, Canada L4K 3C1
Variants:	Refer to Appendix II (this document) – Product Listing/Schedule
Intended Use:	Back Supports are primarily designed as accessories to provide stability, comfort and positioning for wheelchair users, but may have other seating applications.
MD Directive Classification:	Class I
Notified Body:	Not Applicable for Class I devices that are not sterile or have no measuring function.
EU Authorised Representative:	Advena Limited, Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Medical Device Directive Assessment Route:	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

Name: Dona Bhamra **Position:** Senior Quality/Regulatory Affairs Manager

Signed:  **Date:** 09/Sep/2020 (dd/mm/yyyy)

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

	Document ID : TRD0548 Rev B	
	Date: 31-Aug-2020	
MTDC-02	EU Declaration of Conformity	Page 2 of 2

Appendix I – Applicable Standards:

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN 12182:2012	Assistive products for persons with disability. General requirements and test methods
EN 12183:2014	Manual wheelchairs- Requirements and test methods
EN 1021-1/-2:2014	Furniture. Assessment of the ignitability of upholstered furniture -- Part1: Ignition source smouldering cigarette, and Part2: Ignition source: match-flame equivalent
ISO 8191-1/-2:1987/1988	Furniture -- Assessment of the ignitability of upholstered furniture -- Part1: Ignition source: smouldering cigarette (1987), and Part2: Ignition source: match-flame equivalent (1988)
ISO 7176-16:2012	Wheelchairs — Part 16: Resistance to ignition of postural support devices
EN 10993-5:2009	Biological evaluation of medical devices (Part 5: Tests for in-vitro cytotoxicity)
EN 980:2008	Graphical symbols for use with medical devices.

Appendix II – Product Listing/Schedule:

Part/Catalogue Number	Description/Name	GMDN Codes	
Refer to Appendix II – MTDC-02, Product and Accessory Listing, Invacare-Matrix Back Supports, (TRD0549) provided separately		36254	Wheelchair back rest
		41119	Wheelchair headrest
		45887	Wheelchair head/ trunk support
		13356	Wheelchair occupant restraint
		64619	Wheelchair back rest positioner
		64620	Wheelchair back rest positioner pin

Revision History

Revision	Compiled by	Date	Description
A	Paul Patten	31-Oct-2019	First issue; initial release of MTDC-02 Declaration of Conformity and Appendix II (TRD0549)
B	Paul Patten	31-Aug-2020	Appendix II- MTDC-02 (TRD0549) Updated to include Matrix Elite E2 Back and Accessories; updated new GMDN Codes