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EU MDR DECLARATION OF CONFORMITY

**REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL of 5 April 2017**

Legal Manufacturer:	Motion Concepts
Manufacturer Address:	84 Citation Drive, Units 1-9, Concord, Ontario, Canada L4K 3C1
SRN (Single Registration No.)	CA-MF-000004393
Authorised Representative (AR):	Advena Ltd.
AR Address:	Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta
AR SRN	MT-AR-000000234
BASIC UDI-DI	7540147MATRXBACKS98
Product Name:	Invacare-Matrx Back Supports and Accessories.
Product Codes:	Refer to Product Variant Listing provided. <i>(see also <u>Appendix I</u>, Product and Accessory List, Invacare-Matrx Back Supports)</i>
Intended Purpose:	Anatomically contoured back supports are designed to allow precise orientation of a person within a wheelchair and to provide optimal postural support, comfort, and positioning for wheelchair users.
Classification:	Class I
Notified Body:	Not Applicable for Class I devices that are non-sterile, non-invasive, and non-measuring
Conformity Assessment Route:	Self-certification by Medical Device Regulation MDR 2017/745, based on EU Declaration of Conformity and Article 19; and in accordance with technical documentation requirements of Annex II and III.

This declaration of conformity is issued under the sole responsibility of Motion Concepts in compliance to Article 19 of EU MDR 2017/745. We hereby declare that the medical device specified above meet the provision of the Annex IV of Regulation EU MDR 2017/745 for medical devices.

Signature:



Dona Bhamra
Director of Quality and
Regulatory Affairs

signed at Motion Concepts LP, Canada, on

2-Apr-2024

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Applicable Standards:

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

Standard Name	Description
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
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
ISO 16840-10:2021	Wheelchair seating — Part 10: Resistance to ignition of postural support devices — Requirements and test method
EN 10993-5:2009	Biological evaluation of medical devices (Part 5: Tests for in-vitro cytotoxicity)
EN 10993-10:2010	Biological evaluation of medical devices (Part 10: Tests for irritation and skin sensitization)
ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
ISO 15223-1:2012	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
ISO 21856:2022	Assistive products- General requirements and test methods
EN 12183:2022	Manual wheelchairs- Requirements and test methods

Product Variant Listing:

Model/Catalogue Number	Description/Name	GMDN Codes	
For a more detailed summary of devices and configurations, refer to Appendix I (DC-MT-002), Product and Accessory List, Invacare-Matrx Back Supports , 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
		EMDN Codes	
		V080302	Patient Positioning Medical Cushions
		V0880	Medical Support Equipment- Accessories
		Y122499	Wheelchair Accessories- Other

DEVICE DESCRIPTION	UDI-DI	PRODUCT CODE	GMDN Code	EMDN Codes
Matrx PB Deep HD Back	07540147000011	DHD	36254	V080302
Matrx Elite Deep Back	07540147000028	EDB-NH	36254	V080302
Matrx PB Back	07540147000035	MPB-NH	36254	V080302
Matrx PB HD Back	07540147000042	HDB	36254	V080302
Matrx PB Deep Back	07540147000059	PBD-NH	36254	V080302





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Matrx Elite Back	07540147000066	PBE-NH		36254	V080302	
Matrx Elite TR Back	07540147000097	PBE-TR-NH		36254	V080302	
Matrx Elite TR HD Back	07540147000103	PBE-HDTR		36254	V080302	
Matrx Elite Deep HD Back	07540147000110	EDB-HD		36254	V080302	
Matrx Mini Back	07540147000127	MINI		36254	V080302	
Matrx MX2 Back	07540147000141	IMX2-NH		36254	V080302	
Matrx Elite HD Back	07540147000158	PBE-HD		36254	V080302	
EasySet Hardware	07540147000165	PBMH		64619	V0880	Y122499
HD EasySet Hardware	07540147000172	HDMH		64619	V0880	Y122499
MiniSet Hardware	07540147000189	MSMH		64619	V0880	Y122499
MiniSet HD Hardware	07540147000196	MSHD		64619	V0880	Y122499
Fixed Space Saver Hardware	07540147000202	FSSH		64619	V0880	Y122499
Split Mounting Hardware	07540147000219	SMH		64619	V0880	Y122499
Extended Range Mtg Hardware Upgrade	07540147000226	ERMHU		64619	V0880	Y122499
EasySet Hardware (fits 1-1/8")	07540147000233	PBMH-Q		64619	V0880	Y122499
ETAC Mounting Hardware	07540147000240	ETMH		64619	V0880	Y122499
MX2 Fixed Hardware	07540147000264	IMX2CFH		64619	V0880	Y122499
MX2 Fixed HD Hardware	07540147000271	IMX2CFH-HD		64619	V0880	Y122499
MX2 Removable Hardware	07540147000288	IMX2QRH		64619	V0880	Y122499
MX2 Removable HD Hardware	07540147000295	IMX2QRH-HD		64619	V0880	Y122499
Chest Harness Interface-Mini Back (2 pc)	07540147000301	HIMINI		13356	V0880	Y122499
Elan Mini Headrest Mtg Hardware	07540147000318	MEMH	MEMH-EXT	41119	V0880	Y122499
Elan Std. Headrest Mtg Hardware	07540147000325	MEHW	MEHW-EXT	41119	V0880	Y122499
Elite Headrest Adapters (All sizes)	07540147000332	EHRA		41119	V0880	Y122499
Elan Standard Headrest Pads	07540147000349	ESP		41119	V0880	Y122499
Elan Standard Headrest Covers	07540147000356	ESC		41119	V0880	Y122499
LOXX Standard Headrest Hardware	07540147000363	LXSHW		41119	V0880	Y122499
Matrx Headrest Mtg Plate Kit Only	07540147000370	MHMMPK		41119	V0880	Y122499
Headrest Adapter for IVC Rea Flex3	07540147000387	FLEX3A		41119	V0880	Y122499
IVC Rea Headrest Adapter (Matrx Headrests)	07540147000394	FLEX3TAB		41119	V0880	Y122499
Elan Head Band	07540147000400	ELHB		13356	V0880	Y122499
LOXX Mini Headrest Hardware	07540147000417	LXMMH		41119	V0880	Y122499
Matrx E2 Standard Back	07540147000424	E2S		36254	V080302	
Matrx E2 Deep Back	07540147000431	E2D		36254	V080302	
Loxx Headrest Kit (incl. Elan Headrest Pad)	07540147000448	LXHK		41119	V0880	Y122499



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Elite Swing-Away Laterals- Hardware Only	07540147000462	SAHEB		45887	V0880	Y122499
Elite Lateral Pads (All Models)	07540147000479	EPAD		45887	V0880	Y122499
MX2 Fixed Laterals	07540147000486	MXLAT		45887	V0880	Y122499
Mini Fixed Laterals	07540147000493	MINILAT		45887	V0880	Y122499
Elite Swing-Away Lateral Pads & Hardware	07540147000509	SALEB		45887	V0880	Y122499
E2 Fixed Laterals	07540147000516	E2FL		45887	V0880	Y122499
Chest Harness interface- PB Back	07540147000523	CHIPB		13356	V0880	Y122499
Chest Harness Interface- Elite Back	07540147000530	CHIEB		13356	V0880	Y122499
Chest Harness Interface-Mini Back (1 pc)	07540147000547	CHIMB		13356	V0880	Y122499
MiniFlex Abdominal Support	07540147000554	MINIFLEX		13356	V0880	Y122499
Privacy Flaps	07540147000561	PLFAP		36254	V0880	Y122499
Mini Back Hardware Extension Kit	07540147000608	MINI-EXT		64619	V0880	Y122499
Matrx Mounting Hardware (Roxx Wheelchair)	07540147000615	ROXMH		64619	V0880	Y122499
Extended Mounting Pins	07540147000622	EMP		64620	V0880	Y122499
Matrx PB Deep HD Cover	07540147000639	DDC		36254	V080302	
Matrx Elite Deep Cover	07540147000646	EDBC		36254	V080302	
Matrx Elite Deep HD Cover	07540147000653	EDBC-HD		36254	V080302	
Matrx PB Cover	07540147000660	PBC		36254	V080302	
Matrx PB HD Cover	07540147000677	HDC		36254	V080302	
Matrx PB Deep Cover	07540147000684	DMC		36254	V080302	
Matrx Elite Cover	07540147000691	PBEC		36254	V080302	
Matrx Elite HD Cover	07540147000707	PBEC-HD		36254	V080302	
Matrx Elite TR Cover	07540147000714	PBEC-TR		36254	V080302	
Matrx Elite TR HD Cover	07540147000721	PBEC-HDTR		36254	V080302	
Matrx Mini Back Cover	07540147000738	MC-K		36254	V080302	
Matrx MX2 Back Cover	07540147000745	IMXC		36254	V080302	
E2 chest harness interface	07540147000844	E2CHI		13356	V0880	Y122499
E2 Backbone	07540147000851	E2BKB		41119	V0880	Y122499
E2 Headrest Interface	07540147000868	E2HI	E2HDI	41119	V0880	Y122499
E2 MiniSet Fixed Hardware	07540147000882	MSFX		64619	V0880	Y122499
E2 EasySet Fixed Hardware	07540147000899	ESFX		64619	V0880	Y122499
Posture Flex Abdominal Support	07540147000905	PFLEX		13356	V0880	Y122499
Matrx E2 Standard Back Cover	07540147000912	E2SC		36254	V080302	
Matrx E2 Deep Back Cover	07540147000929	E2DC		36254	V080302	
Posture Flex Quad Release Tab	07540147000936	QRTAB		13356	V0880	Y122499



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Protect E2 Standard Cover (IC)	07540147000943	PROTE2S		36254	V080302	Y122499
Protect E2 Deep Cover (IC)	07540147000950	PROTE2D		36254	V080302	Y122499
Elite Offset Swing-Away Laterals- Hardware Only	07540147001056	OSAH		45887	V0880	Y122499
Mini Swing-Away Laterals- Hardware Only	07540147001063	SAHMINI		45887	V0880	Y122499
Elite Offset S/A Lateral Pads & Hardware	07540147001070	OSALEB		45887	V0880	Y122499
Mini Swing-Away Lateral Pads & Hardware	07540147001087	SAHMINI		45887	V0880	Y122499
Elan Occipital Headrest Pads	07540147001094	EOP		41119	V0880	Y122499
Elan 4-Point Headrest Pads	07540147001100	E4POINT	E4PTSM	41119	V0880	Y122499
Elan 4-Point Headrest Pads with Headband	07540147001117	E4PTSHB	E4PTLHB	41119	V0880	Y122499
Elan Occipital Headrest Cover	07540147001124	EOC		41119	V0880	Y122499
Elan 4-Point Headrest Cover	07540147001131	EC4POINT	EC4PTSM	41119	V0880	Y122499
Elan 4-Point Headrest Cover, 2-Way Zipper	07540147001148	C2Z-E4PTSHB	C2Z-E4PTLHB	41119	V0880	Y122499
Elite Fixed Lateral Supports- Standard	07540147001155	PBL5		45887	V0880	Y122499
Elite Fixed Lateral Supports- Small	07540147001162	PB55		45887	V0880	Y122499
Elite Fixed Offset Lateral Supports	07540147001179	PBOL		45887	V0880	Y122499
E2 Removable MiniSet Hardware	07540147001186	E2MMH		64619	V0880	Y122499
E2 Removable EasySet Hardware	07540147001193	E2EMH		64619	V0880	Y122499
E2 Removable HD MiniSet Hardware	07540147001209	E2MSHD		64619	V0880	Y122499
E2 Removable HD EasySet Hardware	07540147001216	E2HDMH		64619	V0880	Y122499
E2 Split Mounting Hardware	07540147001223	E2SMH		64619	V0880	Y122499
E2 Removable EasySet Hardware (fits 1-1/8" canes)	07540147001230	E2PBMH-Q		64619	V0880	Y122499
E2 Extended Range Mounting Hardware	07540147001254	E2ERMH		64619	V0880	Y122499
Matrix MAC Back	07540147001377	MAC		36254	V080302	
Matrix MAC Lateral Contours	07540147001384	MLC		45887	V0880	Y122499
Matrix MAC-HUG Back	07540147001391	MAC-HUG		36254	V080302	
Matrix Flipp-Elan Headrest Hardware	07540147001407	FPE		41119	V0880	Y122499
Matrix Flipp-Loxx Headrest Hardware	07540147001414	FPLX		41119	V0880	Y122499
Matrix Hug Headrest Pad & Cover	07540147001421	ESx-HUG		41119	V0880	Y122499
Matrix Hug Headrest Pad, Insert Only	07540147001438	HUG-HRPAD	ESx-IC-HUG	41119	V0880	Y122499
Matrix MAC-HUG Insert-Only	07540147001445	HUGI		36254	V080302	
Matrix MAC Back Cover (Foam)	07540147001452	MACC		36254	V080302	
Matrix MAC Back Cover (HUG insert)	07540147001469	MACC-H		36254	V080302	

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Revision History:

Rev.	Author	Effective Date	Change Order	Revision Description
A	Paul Patten	18-May-2021	DCN-2933	Initial release.
B	Paul Patten	10-Jun-2022	DCN-3145	Updated Applicable Standards to include ISO 20417:2021; Added Loxx Headrest Hardware options: LXSHW, LXMMH, LXHK.
C	Paul Patten	28-Mar-2023	DCN-3251	DoC updated to reference UDI Codes; DOC and Appendix I updated: Added new hardware options: E2EMH, E2MMH, E2MSHD, E2HDMH, E2ERMH, CHIMB; Removed: WSC, MAHW, PHRK, PBCR, PBCI (discontinued); Corrected device codes for Matrx PBD, DHD and IMX2 Back Covers (revised to DDC, DMC, IMXC); Corrected device codes for LOXX headrest hardware: (revised to LXSHW and LXMMH)
D	Paul Patten	2-May-2023	DCN-3287	Updates to Applicable Standards; added EUDAMED (EDMN) Codes to Product Listing
E	Paul Patten	09-Apr-2024	DCN-3509	Added devices: MAC, MAC-HUG, MLC, FPE, FPLX, ESx-HUG, HUG-HRPAD, HUGI, MACC, MACC-H

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