

	<b>EU DECLARATION OF CONFORMITY</b>	DC-MT-001	Rev	A
	Device: <b>Invacare-Matrx Seat Cushions &amp; Accessories</b>	Page 1 of 5		

## EU MDR DECLARATION OF CONFORMITY

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

<b>Legal Manufacturer:</b>	Motion Concepts
<b>Manufacturer Address:</b>	84 Citation Drive, Units 1-9, Concord, Ontario, Canada L4K 3C1
<b>SRN (Single Registration No.)</b>	CA-MF-000004393
<b>Authorised Representative (AR):</b>	Advena Ltd.
<b>AR Address:</b>	Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta.
<b>AR SRN:</b>	MT-AR-000000234
<b>BASIC UDI-DI</b>	7540147MATRXSEATSGG
<b>Product Name:</b>	Invacare-Matrx Seat Cushions and Accessories.
<b>Product Variants:</b>	Refer to Product Variant Listing provided. <i>(see also <u>Appendix I, Product and Accessory List, Invacare-Matrx Seat Cushions</u>)</i>
<b>Intended Purpose:</b>	Anatomically contoured seat cushions designed to provide positioning, stability, skin protection, and added comfort to wheelchair users.
<b>Classification:</b>	Class I
<b>Notified Body:</b>	Not Applicable for Class I devices that are non-sterile, non-invasive, and non-measuring
<b>Conformity Assessment Route:</b>	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:

*signed at Motion Concepts LP, Canada, on*



17-May-2021

**Dona Bhamra**  
Senior Quality and Regulatory  
Affairs Manager

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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
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)
EN 1041(2008)+A1(2013)	Information supplied by the manufacturer of medical devices
ISO 15223-1:2012	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
EN 12182:2012	Assistive products for persons with disability. General requirements and test methods
EN 12183:2014	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 <b>Appendix I (DC-MT-001), Product and Accessory List, Invacare-Matrx Seat Cushions</b> , provided separately		<b>44361</b>	Foam filled chair cushion
		<b>62720</b>	Medical Cushion Cover
		<b>37744</b>	Wheelchair bracket

Invacare-Matrx Kidabra-Vi Cushions/Bases				
Model # (Europe)	Model # (North America)	GMDN Code	Model # Extra Outer Cover	GMDN Code
KA3131-Vi	KA1212-Vi	44361	KC3131	62720
KA3136-Vi	KA1214-Vi	44361	KC3136	62720
KA3631-Vi	KA1412-Vi	44361	KC3631	62720
KA3636-Vi	KA1414-Vi	44361	KC3636	62720
KB3131-Vi	KB1212-Vi	44361	KBC3131	62720
KB3136-Vi	KB1214-Vi	44361	KBC3136	62720
KB3331-Vi	KB1312-Vi	44361	KBC3331	62720
KB3336-Vi	KB1314-Vi	44361	KBC3336	62720
KB3631-Vi	KB1412-Vi	44361	KBC3631	62720
KB3636-Vi	KB1414-Vi	44361	KBC3636	62720





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Invacare-Matrix-Vi Cushions/Bases				
Model # (Europe)	Model # (North America)	GMDN Code	Model # Extra Outer Cover	GMDN Code
MA3638-Vi	MA1415-Vi	44361	C3638	62720
MA3643-Vi	MA1417-Vi	44361	C3643	62720
MA4141-Vi	MA1616-Vi	44361	C4141	62720
MA4146-Vi	MA1618-Vi	44361	C4146	62720
MA4151-Vi	MA1620-Vi	44361	C4151	62720
MA4641-Vi	MA1816-Vi	44361	C4641	62720
MA4646-Vi	MA1818-Vi	44361	C4646	62720
MA4651-Vi	MA1820-Vi	44361	C4651	62720
MA5141-Vi	MA2016-Vi	44361	C5141	62720
MA5146-Vi	MA2018-Vi	44361	C5146	62720
MA5151-Vi	MA2020-Vi	44361	C5151	62720
MA5646-Vi	MA2218-Vi	44361	C5646	62720
MA5651-Vi	MA2220-Vi	44361	C5651	62720
MAWWDD-Vi	MAWWDD-Vi	44361	CWWDD	62720
MB3638-Vi	MB1415-Vi	44361	BC3638	62720
MB3643-Vi	MB1417-Vi	44361	BC3643	62720
MB3841-Vi	MB1516-Vi	44361	BC3841	62720
MB3846-Vi	MB1518-Vi	44361	BC3846	62720
MB4141-Vi	MB1616-Vi	44361	BC4141	62720
MB4146-Vi	MB1618-Vi	44361	BC4146	62720
MB4341-Vi	MB1716-Vi	44361	BC4341	62720
MB4346-Vi	MB1718-Vi	44361	BC4346	62720
MB4641-Vi	MB1816-Vi	44361	BC4641	62720
MB4646-Vi	MB1818-Vi	44361	BC4646	62720
MB4841-Vi	MB1916-Vi	44361	BC4841	62720
MB4846-Vi	MB1918-Vi	44361	BC4846	62720
MB5141-Vi	MB2016-Vi	44361	BC5141	62720
MB5146-Vi	MB2018-Vi	44361	BC5146	62720

Invacare-Matrix Base Cushion Hardware			
Model # (Europe)	Model # (North America)	GMDN Code	Description
BDH0	BDH0	37744	Flush Hooks (pair)
BDH1-22	BDH1-7/8"	37744	1" (26mm) Drop Hooks (pair)
BDH2-22	BDH2-7/8"	37744	2" (51mm) Drop Hooks (pair)
BDH1-26	BDH1-1	37744	1" (26mm) Drop Hooks (pair)
BDH2-26	BDH2-1	37744	2" (51mm) Drop Hooks (pair)



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Invacare-Matrx PS Cushions				
Model # (Europe)	Model # (North America)	GMDN Code	Model # Extra Outer Cover	GMDN Code
PS2626-K	PS1010-K	44361	PSC2626-K	62720
PS2631-K	PS1012-K	44361	PSC2631-K	62720
PS2636-K	PS1014-K	44361	PSC2636-K	62720
PS2826-K	PS1112-K	44361	PSC2826-K	62720
PS2831-K	PS1114-K	44361	PSC2831-K	62720
PS2836-K	PS1116-K	44361	PSC2836-K	62720
PS3131-K	PS1212-K	44361	PSC3131-K	62720
PS3136-K	PS1214-K	44361	PSC3136-K	62720
PS3141-K	PS1216-K	44361	PSC3141-K	62720
PS3331-K	PS1312-K	44361	PSC3331-K	62720
PS3336-K	PS1314-K	44361	PSC3336-K	62720
PS3341-K	PS1316-K	44361	PSC3341-K	62720
PS3631-K	PS1412-K	44361	PSC3631-K	62720
PS3636-K	PS1414-K	44361	PSC3636-K	62720
PS3641-K	PS1416-K	44361	PSC3641-K	62720
PS4141	PS1616	44361	PSC4141	62720
PS4146	PS1618	44361	PSC4146	62720
PS4151	PS1620	44361	PSC4151	62720
PS4641	PS1816	44361	PSC4641	62720
PS4646	PS1818	44361	PSC4646	62720
PS4651	PS1820	44361	PSC4651	62720
PS5141	PS2016	44361	PSC5141	62720
PS5146	PS2018	44361	PSC5146	62720
PS5151	PS2020	44361	PSC5151	62720
PS5646	PS2218	44361	PSC5646	62720
PS5651	PS2220	44361	PSC5651	62720
PS5656	PS2222	44361	PSC5656	62720
PS6146	PS2418	44361	PSC6146	62720
PS6151	PS2420	44361	PSC6151	62720
PS6156	PS2422	44361	PSC6156	62720
PS6646	PS2618	44361	PSC6646	62720
PS6651	PS2620	44361	PSC6651	62720
PS6656	PS2622	44361	PSC6656	62720

(-K) = Kidabra Fabric



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Invacare-Matrx Seat Cushion Accessories			
Model # (Europe)	Model # (North America)	GMDN Code	Description
POK	POK	44361	Pelvic Obliquity Kit (2 foam inserts)
PROTMC-4141	PROTMC-1616	62720	Protect Slipcover- for Matrx Cushions
PROTMC-4146	PROTMC-1618	62720	Protect Slipcover- for Matrx Cushions
PROTMC-4151	PROTMC-1620	62720	Protect Slipcover- for Matrx Cushions
PROTMC-4641	PROTMC-4641	62720	Protect Slipcover- for Matrx Cushions
PROTMC-4646	PROTMC-4646	62720	Protect Slipcover- for Matrx Cushions
PROTMC-4651	PROTMC-4651	62720	Protect Slipcover- for Matrx Cushions
PROTMC-5141	PROTMC-5141	62720	Protect Slipcover- for Matrx Cushions
PROTMC-5146	PROTMC-5146	62720	Protect Slipcover- for Matrx Cushions
PROTMC-5151	PROTMC-5151	62720	Protect Slipcover- for Matrx Cushions
CR36S	CR14S	62720	Seat Cushion Rigidizer
CR41S	CR16S	62720	Seat Cushion Rigidizer
CR41M	CR16M	62720	Seat Cushion Rigidizer
CR41L	CR16L	62720	Seat Cushion Rigidizer
CR46S	CR18S	62720	Seat Cushion Rigidizer
CR46M	CR18M	62720	Seat Cushion Rigidizer
CR46L	CR18L	62720	Seat Cushion Rigidizer
CR51S	CR20S	62720	Seat Cushion Rigidizer
CR51M	CR20M	62720	Seat Cushion Rigidizer
CR51L	CR20L	62720	Seat Cushion Rigidizer
CR56M	CR22M	62720	Seat Cushion Rigidizer
CR56L	CR22L	62720	Seat Cushion Rigidizer

### Revision History:

Rev.	Author	Effective Date	Change Order	Revision Description
A	Paul Patten	18-May-2021	DCN-2933	Initial release.

**\*\*END OF DOCUMENT\*\***





**DC-MT-001, Appendix I, Product and Accessory List: IVC-Matrix Seat Cushions**

Invacare MaTRx-Vi Cushion						
Model # (Europe)	Model # (North America)	GMDN Code	Fits Wheelchair		Model #	GMDN Code
			Width	Depth	Extra Outer Cover	
MA3638-Vi	MA1415-Vi	44361	33cm-36cm	38cm-41cm	C3638	62720
MA3643-Vi	MA1417-Vi	44361	33cm-36cm	43cm-46cm	C3643	62720
MA4141-Vi	MA1616-Vi	44361	38cm-41cm	41cm-43cm	C4141	62720
MA4146-Vi	MA1618-Vi	44361	38cm-41cm	46cm-48cm	C4146	62720
MA4151-Vi	MA1620-Vi	44361	38cm-41cm	51cm-53cm	C4151	62720
MA4641-Vi	MA1816-Vi	44361	43cm-46cm	41cm-43cm	C4641	62720
MA4646-Vi	MA1818-Vi	44361	43cm-46cm	46cm-48cm	C4646	62720
MA4651-Vi	MA1820-Vi	44361	43cm-46cm	51cm-53cm	C4651	62720
MA5141-Vi	MA2016-Vi	44361	48cm-51cm	41cm-43cm	C5141	62720
MA5146-Vi	MA2018-Vi	44361	48cm-51cm	46cm-48cm	C5146	62720
MA5151-Vi	MA2020-Vi	44361	48cm-51cm	51cm-53cm	C5151	62720
MA5646-Vi	MA2218-Vi	44361	53cm-56cm	46cm-48cm	C5646	62720
MA5651-Vi	MA2220-Vi	44361	53cm-56cm	51cm-53cm	C5651	62720

Invacare MaTRx-Vi Heavy Duty Cushion						
Model # (Europe)	Model # (North America)	GMDN Code	Cushion Width	Cushion Depth	Model #	GMDN Code
					Extra Outer Cover	
MAWWDD-Vi	MAWWDD-Vi	44361	53cm-66cm*	46cm-76cm*	CWWDD	62720

(\* 1" (2.5cm increments)

Invacare Matrix Kidabra-Vi Cushion						
Model # (Europe)	Model # (North America)	GMDN Code	Fits Wheelchair		Model #	GMDN Code
			Width	Depth	Extra Outer Cover	
KA3131-Vi	KA1212-Vi	44361	28cm-31cm	31cm-33cm	KC3131	62720
KA3136-Vi	KA1214-Vi	44361	28cm-31cm	36cm-38cm	KC3136	62720
KA3631-Vi	KA1412-Vi	44361	33cm-36cm	31cm-33cm	KC3631	62720
KA3636-Vi	KA1414-Vi	44361	33cm-36cm	36cm-38cm	KC3636	62720

Invacare MaTRX-Vi Base						
Model # (Europe)	Model # (North America)	GMDN Code	Fits Wheelchair		Model #	GMDN Code
			Width	Depth	Extra Outer Cover	
MB3638-Vi	MB1415-Vi	44361	36cm	38cm-41cm	BC3638	62720
MB3643-Vi	MB1417-Vi	44361	36cm	43cm-46cm	BC3643	62720
MB3841-Vi	MB1516-Vi	44361	38cm	41cm-43cm	BC3841	62720
MB3846-Vi	MB1518-Vi	44361	38cm	46cm-48cm	BC3846	62720
MB4141-Vi	MB1616-Vi	44361	41cm	41cm-43cm	BC4141	62720
MB4146-Vi	MB1618-Vi	44361	41cm	46cm-48cm	BC4146	62720
MB4341-Vi	MB1716-Vi	44361	43cm	41cm-43cm	BC4341	62720
MB4346-Vi	MB1718-Vi	44361	43cm	46cm-48cm	BC4346	62720



MB4641-Vi	MB1816-Vi	44361	46cm	41cm-43cm	BC4641	62720
MB4646-Vi	MB1818-Vi	44361	46cm	46cm-48cm	BC4646	62720
MB4841-Vi	MB1916-Vi	44361	48cm	41cm-43cm	BC4841	62720
MB4846-Vi	MB1918-Vi	44361	48cm	46cm-48cm	BC4846	62720
MB5141-Vi	MB2016-Vi	44361	51cm	41cm-43cm	BC5141	62720
MB5146-Vi	MB2018-Vi	44361	51cm	46cm-48cm	BC5146	62720

**Invacare Matrix Kidabra-Vi Base**

Model # (Europe)	Model # (North America)	GMDN Code	Fits Wheelchair		Model # Extra Outer Cover	GMDN Code
			Width	Depth		
KB3131-Vi	KB1212-Vi	44361	31cm	31cm-33cm	KBC3131	62720
KB3136-Vi	KB1214-Vi	44361	31cm	36cm-38cm	KBC3136	62720
KB3331-Vi	KB1312-Vi	44361	31cm	31cm-33cm	KBC3331	62720
KB3336-Vi	KB1314-Vi	44361	33cm	36cm-38cm	KBC3336	62720
KB3631-Vi	KB1412-Vi	44361	33cm	31cm-33cm	KBC3631	62720
KB3636-Vi	KB1414-Vi	44361	36cm	36cm-38cm	KBC3636	62720

**Invacare Matrix Vi/Kidabra-Vi Base Hardware**

Model # (Europe)	Model # (North America)	GMDN Code	Description		GMDN Code
			all tubing	Flush Hooks (pair)	
BDH0	BDH0	37744	all tubing	Flush Hooks (pair)	62720
BDH1-22	BDH1-7/8"	37744	fits 22mm tubing	1" (26mm) Drop Hooks (pair)	62720
BDH2-22	BDH2-7/8"	37744	fits 22mm tubing	2" (51mm) Drop Hooks (pair)	62720
BDH1-26	BDH1-1	37744	fits 26mm tubing	1" (26mm) Drop Hooks (pair)	62720
BDH2-26	BDH2-1	37744	fits 26mm tubing	2" (51mm) Drop Hooks (pair)	62720
BDC	BDC	37744	all tubes	DuraClip hardware (pair)	62720
BFC	BFC	37744	all tubes	FixClip hardware (pair)	62720

**Invacare MaTRx-PS Cushion**

Model # (Europe)	Model # (North America)	GMDN Code	Fits Wheelchair		Model # Extra Outer Cover	GMDN Code
			Width	Depth		
PS2626-K	PS1010-K	44361	23cm-26cm	26cm-28cm	PSC2626-K	62720
PS2631-K	PS1012-K	44361	23cm-26cm	31cm-33cm	PSC2631-K	62720
PS2636-K	PS1014-K	44361	23cm-26cm	36cm-38cm	PSC2636-K	62720
PS2826-K	PS1112-K	44361	26cm-28cm	31cm-33cm	PSC2826-K	62720
PS2831-K	PS1114-K	44361	26cm-28cm	36cm-38cm	PSC2831-K	62720
PS2836-K	PS1116-K	44361	26cm-28cm	41cm-43cm	PSC2836-K	62720
PS3131-K	PS1212-K	44361	28cm-31cm	31cm-33cm	PSC3131-K	62720
PS3136-K	PS1214-K	44361	28cm-31cm	36cm-38cm	PSC3136-K	62720
PS3141-K	PS1216-K	44361	28cm-31cm	41cm-43cm	PSC3141-K	62720
PS3331-K	PS1312-K	44361	31cm-33cm	31cm-33cm	PSC3331-K	62720
PS3336-K	PS1314-K	44361	31cm-33cm	36cm-38cm	PSC3336-K	62720
PS3341-K	PS1316-K	44361	31cm-33cm	41cm-43cm	PSC3341-K	62720
PS3631-K	PS1412-K	44361	33cm-36cm	31cm-33cm	PSC3631-K	62720
PS3636-K	PS1414-K	44361	33cm-36cm	36cm-38cm	PSC3636-K	62720
PS3641-K	PS1416-K	44361	33cm-36cm	41cm-43cm	PSC3641-K	62720
PS4141	PS1616	44361	38cm-41cm	41cm-43cm	PSC4141	62720
PS4146	PS1618	44361	38cm-41cm	46cm-48cm	PSC4146	62720
PS4151	PS1620	44361	38cm-41cm	51cm-53cm	PSC4151	62720
PS4641	PS1816	44361	43cm-46cm	41cm-43cm	PSC4641	62720
PS4646	PS1818	44361	43cm-46cm	46cm-48cm	PSC4646	62720



PS4651	PS1820	44361	43cm-46cm	51cm-53cm	PSC4651	62720
PS5141	PS2016	44361	48cm-51cm	41cm-43cm	PSC5141	62720
PS5146	PS2018	44361	48cm-51cm	46cm-48cm	PSC5146	62720
PS5151	PS2020	44361	48cm-51cm	51cm-53cm	PSC5151	62720
PS5646	PS2218	44361	53cm-56cm	46cm-48cm	PSC5646	62720
PS5651	PS2220	44361	53cm-56cm	51cm-53cm	PSC5651	62720
PS5656	PS2222	44361	53cm-56cm	56cm-58cm	PSC5656	62720
PS6146	PS2418	44361	58cm-61cm	46cm-48cm	PSC6146	62720
PS6151	PS2420	44361	58cm-61cm	51cm-53cm	PSC6151	62720
PS6156	PS2422	44361	58cm-61cm	56cm-58cm	PSC6156	62720
PS6646	PS2618	44361	63cm-66cm	46cm-48cm	PSC6646	62720
PS6651	PS2620	44361	63cm-66cm	51cm-53cm	PSC6651	62720
PS6656	PS2622	44361	63cm-66cm	56cm-58cm	PSC6656	62720

-K) = Kidabra Fabric

Invacare MaTRx PS Heavy Duty Cushion						
Model # (Europe)	Model # (North America)	GMDN Code	Cushion Width	Cushion Depth	Model # Extra Outer Cover	GMDN Code
PSWWDD	PSWWDD	44361	53cm-76cm*	46cm-76cm*	PSCWWDD	62720

(\* 1" (2.5cm increments)

Invacare Matrix Seat Cushion Accessories			
Model # (Europe)	Model # (North America)	GMDN Code	Description
POK	POK	44361	Pelvic Obliquity Kit (2 foam inserts)
CR36S	CR14S	62720	Seat Cushion Rigidizer
CR41S	CR16S	62720	Seat Cushion Rigidizer
CR41M	CR16M	62720	Seat Cushion Rigidizer
CR41L	CR16L	62720	Seat Cushion Rigidizer
CR46S	CR18S	62720	Seat Cushion Rigidizer
CR46M	CR18M	62720	Seat Cushion Rigidizer
CR46L	CR18L	62720	Seat Cushion Rigidizer
CR51S	CR20S	62720	Seat Cushion Rigidizer
CR51M	CR20M	62720	Seat Cushion Rigidizer
CR51L	CR20L	62720	Seat Cushion Rigidizer
CR56M	CR22M	62720	Seat Cushion Rigidizer
CR56L	CR22L	62720	Seat Cushion Rigidizer
PROTMC-4141	PROTMC-1616	62720	Protect Slipcover- for Matrix Cushions
PROTMC-4146	PROTMC-1618	62720	Protect Slipcover- for Matrix Cushions
PROTMC-4151	PROTMC-1620	62720	Protect Slipcover- for Matrix Cushions
PROTMC-4641	PROTMC-4641	62720	Protect Slipcover- for Matrix Cushions
PROTMC-4646	PROTMC-4646	62720	Protect Slipcover- for Matrix Cushions
PROTMC-4651	PROTMC-4651	62720	Protect Slipcover- for Matrix Cushions
PROTMC-5141	PROTMC-5141	62720	Protect Slipcover- for Matrix Cushions
PROTMC-5146	PROTMC-5146	62720	Protect Slipcover- for Matrix Cushions
PROTMC-5151	PROTMC-5151	62720	Protect Slipcover- for Matrix Cushions