

Declaration of Conformity for class I devices

According to MDR 2017/745, Annex IV

Date (yyyy.mm.dd)	Change Description	Author
2023.09.29	Minor change- addition of 18 new SKUs. These are new non-padded & padded hip belt variants using existing components in new combinations of buckles and plastic end fittings.	Susan Cwiertnia
2023.12.12	Corrected Declaration of Conformity- removed component level stock codes and EU Authorized Rep SRN #	Susan Cwiertnia
2024.05.28	Added SRN numbers for Manufacturer and EU Authorized Rep	M. Kosh

Manufacturer

Name: **Bodypoint, Inc.**

Address: 558 1st Ave S, Suite 300, Seattle, WA 98104 USA

SRN: US-MF-000042021

Authorised representative

Name: **Bodypoint Europe, B.V.**

Address: Kerkstraat 29, 7396PG Terwolde, Netherlands

SRN: NL-AR-000017282

We, the manufacturer, declare and ensure with sole responsibility that the below mentioned Medical Device(s) meet(s) the provisions of the Medical Device Regulation 2017/745/EU (MDR) which apply to them. The device(s) covered by the present declaration are in conformity with the MDR 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Product and trade name	Product Code(s)	Basic UDI-DI
Essentials Pelvic Positioning Belt	GB215-L62-B5	8411801GMN0001FL
	GB215-M46-B5	
	GB215-S38-B5	
	GB285-L62-B5	
	GB285-M36-B5	
	GB285-M46-B5	

	GB415-L62-B5
	GB415-M46-B5
	GB415-S38-B5
	GB485-L62-B5
	GB485-M36-B5
	GB485-M46-B5
Padded Pelvic Positioning Belt	HB205-L62-A1
	HB205-L62-A2
	HB205-L62-B1
	HB205-L62-B2
	HB205-L82-A1
	HB205-L82-A2
	HB205-L82-B1
	HB205-L82-B2
	HB205-L92-A1
	HB205-L92-A2
	HB205-L92-B1
	HB205-L92-B2
	HB205-M36-A1
	HB205-M36-A2
	HB205-M36-B1
	HB205-M36-B2
	HB205-M46-A1
	HB205-M46-A2
	HB205-M46-B1
	HB205-M46-B2
	HB209-M40-A1
	HB209-M40-A2
	HB209-M40-B1
	HB209-M40-B2
	HB209-M46-A1
	HB209-M46-A2
	HB209-M46-B1
	HB209-M46-B2
	HB215-L62-A1
	HB215-L62-A2
	HB215-L62-B1
	HB215-L62-B2
	HB215-M36-A1
	HB215-M36-A2
	HB215-M36-B1
	HB215-M36-B2

HB215-M46-A1
HB215-M46-A2
HB215-M46-B1
HB215-M46-B2
HB215-S32-A1
HB215-S32-A2
HB215-S32-B1
HB215-S32-B2
HB215-S38-A1
HB215-S38-A2
HB215-S38-B1
HB215-S38-B2
HB216-L62-A1
HB216-L62-A2
HB216-L62-B1
HB216-L62-B2
HB216-M36-A1
HB216-M36-A2
HB216-M36-B1
HB216-M36-B2
HB216-M46-A1
HB216-M46-A2
HB216-M46-B1
HB216-M46-B2
HB216-S32-A1
HB216-S32-A2
HB216-S32-B1
HB216-S32-B2
HB216-S38-A1
HB216-S38-A2
HB216-S38-B1
HB216-S38-B2
HB219-M40-A1
HB219-M40-A2
HB219-M40-B1
HB219-M40-B2
HB219-M46-A1
HB219-M46-A2
HB219-M46-B1
HB219-M46-B2
HB219-S38-A1
HB219-S38-A2
HB219-S38-B1

HB219-S38-B2
HB225-L62-A1
HB225-L62-A2
HB225-L62-B1
HB225-L62-B2
HB225-M36-A1
HB225-M36-A2
HB225-M36-B1
HB225-M36-B2
HB225-M46-A1
HB225-M46-A2
HB225-M46-B1
HB225-M46-B2
HB229-M40-A1
HB229-M40-A2
HB229-M40-B1
HB229-M40-B2
HB229-M46-A1
HB229-M46-A2
HB229-M46-B1
HB229-M46-B2
HB235-S32-A1
HB235-S32-A2
HB235-S32-B1
HB235-S32-B2
HB235-S38-A1
HB235-S38-A2
HB235-S38-B1
HB235-S38-B2
HB239-S38-A1
HB239-S38-A2
HB239-S38-B1
HB239-S38-B2
HB275-M36-A1
HB275-M36-A2
HB275-M36-B1
HB275-M36-B2
HB275-M46-A1
HB275-M46-A2
HB275-M46-B1
HB275-M46-B2
HB275-S32-A1
HB275-S32-A2

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HB275-S32-B2
HB275-S38-A1
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HB405-L62-A1
HB405-L62-A2
HB405-L62-B1
HB405-L62-B2
HB405-M36-A1
HB405-M36-A2
HB405-M36-B1
HB405-M36-B2
HB405-M46-A1
HB405-M46-A2
HB405-M46-B1
HB405-M46-B2
HB409-M40-A1
HB409-M40-A2
HB409-M40-B1
HB409-M40-B2
HB409-M46-A1
HB409-M46-A2
HB409-M46-B1
HB409-M46-B2
HB415-L62-A1
HB415-L62-A2
HB415-L62-B1
HB415-L62-B2
HB415-M36-A1
HB415-M36-A2
HB415-M36-B1
HB415-M36-B2
HB415-M46-A1
HB415-M46-A2
HB415-M46-B1
HB415-M46-B2
HB415-S32-A1
HB415-S32-A2
HB415-S32-B1
HB415-S32-B2
HB415-S38-A1

HB415-S38-A2
HB415-S38-B1
HB415-S38-B2
HB416-L62-A1
HB416-L62-A2
HB416-L62-B1
HB416-L62-B2
HB416-M36-A1
HB416-M36-A2
HB416-M36-B1
HB416-M36-B2
HB416-M46-A1
HB416-M46-A2
HB416-M46-B1
HB416-M46-B2
HB416-S32-A1
HB416-S32-A2
HB416-S32-B1
HB416-S32-B2
HB416-S38-A1
HB416-S38-A2
HB416-S38-B1
HB416-S38-B2
HB419-M40-A1
HB419-M40-A2
HB419-M40-B1
HB419-M40-B2
HB419-M46-A1
HB419-M46-A2
HB419-M46-B1
HB419-M46-B2
HB419-S38-A1
HB419-S38-A2
HB419-S38-B1
HB419-S38-B2
HB425-L62-A1
HB425-L62-A2
HB425-L62-B1
HB425-L62-B2
HB425-M36-A1
HB425-M36-A2
HB425-M36-B1
HB425-M36-B2

HB425-M46-A1
HB425-M46-A2
HB425-M46-B1
HB425-M46-B2
HB429-M40-A1
HB429-M40-A2
HB429-M40-B1
HB429-M40-B2
HB429-M46-A1
HB429-M46-A2
HB429-M46-B1
HB429-M46-B2
HB435-S32-A1
HB435-S32-A2
HB435-S32-B1
HB435-S32-B2
HB435-S38-A1
HB435-S38-A2
HB435-S38-B1
HB435-S38-B2
HB439-S38-A1
HB439-S38-A2
HB439-S38-B1
HB439-S38-B2
HB475-M46-A1
HB475-M46-A2
HB475-M46-B1
HB475-M46-B2
HB475-S38-A1
HB475-S38-A2
HB475-S38-B1
HB475-S38-B2
HB275-S32-B5
HB275-S38-B5
HB275-M36-B5
HB416-S32-B5
HB416-S38-B5
HB416-M36-B5
HB205-M36-B5
HB205-M46-B5
HB205-L62-B5
HB405-M36-B5
HB405-M46-B5

	HB405-L62-B5
	CM260-M38-ERGO-B2-U
	CM260-M46-ERGO-B2-U
	CM263-S32-ERGO-B2-U
	CM291-S32-B2
	CM291-S38-B2
Hook & Loop Pelvic Positioning Belt	LB205-L62-A1
	LB205-L62-A2
	LB205-L62-B1
	LB205-L62-B2
	LB205-M46-A1
	LB205-M46-A2
	LB205-M46-B1
	LB205-M46-B2
	LB209-M46-A1
	LB209-M46-A2
	LB209-M46-B1
	LB209-M46-B2
	LB225-L62-A1
	LB225-L62-A2
	LB225-L62-B1
	LB225-L62-B2
	LB225-M46-A1
	LB225-M46-A2
	LB225-M46-B1
	LB225-M46-B2
	LB229-M46-A1
	LB229-M46-A2
	LB229-M46-B1
	LB229-M46-B2
	LB235-S38-A1
	LB235-S38-A2
	LB235-S38-B1
	LB235-S38-B2
	LB405-L62-A1
	LB405-L62-A2
	LB405-L62-B1
	LB405-L62-B2
	LB405-M46-A1
	LB405-M46-A2
LB405-M46-B1	
LB405-M46-B2	
LB409-M46-A1	

	LB409-M46-A2
	LB409-M46-B1
	LB409-M46-B2
	LB416-S38-A1
	LB416-S38-A2
	LB416-S38-B1
	LB416-S38-B2
	LB425-L62-A1
	LB425-L62-A2
	LB425-L62-B1
	LB425-L62-B2
	LB425-M46-A1
	LB425-M46-A2
	LB425-M46-B1
	LB425-M46-B2
	LB429-M46-A1
	LB429-M46-A2
	LB429-M46-B1
	LB429-M46-B2
	LB435-S38-A1
	LB435-S38-A2
	LB435-S38-B1
	LB435-S38-B2
Leg Harness Pelvic Positioning Belt	LH600L-A1
	LH600L-A2
	LH600L-B1
	LH600L-B2
	LH600M-A1
	LH600M-A2
	LH600M-B1
	LH600M-B2
	LH600S-A1
	LH600S-A2
	LH600S-B1
	LH600S-B2
Non-padded Pelvic Positioning Belt	NB205L-A1
	NB205L-A2
	NB205L-B1
	NB205L-B2
	NB205L-EXT-A1
	NB205L-EXT-A2

NB205L-EXT-B1
NB205L-EXT-B2
NB205M-A1
NB205M-A2
NB205M-B1
NB205M-B2
NB215L-A1
NB215L-A2
NB215L-B1
NB215L-B2
NB215M-A1
NB215M-A2
NB215M-B1
NB215M-B2
NB215S-A1
NB215S-A2
NB215S-B1
NB215S-B2
NB225L-A1
NB225L-A2
NB225L-B1
NB225L-B2
NB225L-T-A1
NB225L-T-A2
NB225L-T-B1
NB225L-T-B2
NB225M-A1
NB225M-A2
NB225M-B1
NB225M-B2
NB275S-B5-ASM
NB275S-B5-ASM-50
NB285L-B5-ASM
NB285L-B5-ASM-50
NB285M-B5-ASM
NB285M-B5-ASM-50

Photograph:



Intended purpose of the device: Used in a wheelchair as a flexible pelvic positioning support belt to increase sitting stability, maintain or correct posture, and maintain a safe seated position.

Risk class and applicable rule in acc. with Annex VIII: Class I; applicable rule: 1

Common Specifications used: Conforms with EN12183:2022, EN12184:2022, ISO16840-3:2022, ISO16840-10:2021, ISO16840-15:2024, ISO10993-5:2009, REACH compliance

Additional information (if applicable): None

A handwritten signature in blue ink that reads "Matthew Kosh". The signature is written in a cursive style and is positioned above a horizontal line.

Signature

Seattle, WA 2024-May-28

Place and Date of issue

Matthew Kosh, President, Bodypoint, Inc.