



Declaration of Conformity for class I devices

According to MDR 2017/745, Annex IV

Manufacturer

Name: **Bodypoint, Inc.**

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

SRN (if assigned):

Authorised representative

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

Address: Kerkstraat 29, 7396PG Terwolde, Netherlands

SRN (if assigned):

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-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
HB275-S32-B1
HB275-S32-B2
HB275-S38-A1
HB275-S38-A2
HB275-S38-B1
HB275-S38-B2
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
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	
Push-Button Buckle Replacement Cover	FS018C-1	
	FS018D-1	
	FS018E-1	
	FS019C-1	
	FS019D-1	
	FS019E-1	
	FS029C-1	
Belt End-fitting	FS032-2	
	FS033-2	
	FS034-2	
	HKA1-B-1	
	HKA1-G-1	
	HKA1-R-1	
	HKA2-B-1	
	HKA2-G-1	

	HKA2-R-1	
Belt Mounting Hardware	HKA10-14MM-1	
	HKA10-19MM-1	
	HKA31-25MM-1	
	HKA32-25MM-1	
	HKA6-12MM-1	
	HKA6-14MM-1	
	HW200-20-2	
	HW200-90-2	
	HW303-19SHIM-2	
	HW303-B-2	
	HW310-22-A-2	
	HW310-25-A-2	
	HW320-22-2	
	HW320-25-2	
	HW320-27X33-2	
	HW320-29-2	
	HW320-30-2	
	HW320-32-2	
Belt Accessory Pad	PD304-2	
	PD305-2	
	PD306-2	
	PD401-2	
	PD402-2	

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 EN12182, EN12183 and EN12184, ISO16840-3, and BS8625 for pelvic positioning belts (anterior pelvic support)

Additional information (if applicable): None



 Signature

Seattle, WA May-1-2021

 Place and Date of issue

Matthew Kosh, President, Bodypoint, Inc.