



# Declaration of Conformity for class I devices According to MDR 2017/745, Annex IV

## Manufacturer

Name: **Bodypoint, Inc.**

Address: 558 1<sup>st</sup> 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
Trunk Support Harness	SH224S	8411801GMN0003FQ
	SH224M	
	SH224L	
	SH224XL	
	SH235L	
	SH235M	
	SH235S	
	SH290L	
	SH290M	
	SH290S	
	SH290XL	
	SH290XS	
	SH290XXS	
	SH295L	
	SH295M	
	SH295S	
	SH295XL	
	SH295XS	
	SH295XXS	
	SH350L	
	SH350M	
	SH350S	
	SH350XL	
	SH351L	
	SH351M	
	SH351S	
	SH351XL	
	SH351XS	
	SH360L	
	SH360M	
SH360XL		

	SH361L	
	SH361M	
	SH361XL	
<b>Harness Strap Guide</b>	HW100-150-2	
	HW100-200-2	
<b>Fastener Pack</b>	HW101P-1	
<b>Mounting Adapters</b>	HW105L-1	
	HW105S-1	
<b>Top Straps</b>	SH025-2	

**Photograph:**



**Intended purpose of the device:** Used in a wheelchair as a flexible anterior trunk support 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 BS8625, ISO16840-15, and ISO16840-3 (anterior trunk support).

**Additional information (if applicable):** None

*Matthew Kosh*

Signature

Seattle, WA May-11-2021

Place and Date of issue

*Matthew Kosh, President, Bodypoint, Inc.*