

Declaration of Conformity for class I devices

According to MDR 2017/745, Annex IV

Date (yyyy.mm.dd)	Change Description	Author
2023.12.12	Corrected Declaration of Conformity- Removed stock codes for items at component level 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.**

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SRN: US-MF-000042021

Authorised representative

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

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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
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
CM261M-ERGO-B2-U
CM261S-ERGO-B2-U
CM261XS-ERGO-B2-U

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 ISO16840-15:2024, and ISO16840-3:2022, ISO10993-5:2009, REACH compliance

Additional information (if applicable): None



Signature

Seattle, WA 2024-May-28

Place and Date of issue

Matthew Kosh, President, Bodypoint, Inc.