

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
Chest Support Belt	SH102-B1	8411801GMN0004FS
	SH102-B2	
	SH102P-B1	
	SH102P-B2	
	SH120L-B1	
	SH120L-B2	
	SH120L-B3	
	SH120M-B1	
	SH120M-B2	
	SH120M-B3	
	SH120S-B1	
	SH120S-B2	
	SH120S-B3	
	SH120XL-B1	
	SH120XL-B2	
	SH120XL-B3	
	SH120XS-B1	
	SH120XS-B2	
	SH120XS-B3	
	SH122L-B1	
	SH122L-B2	
	SH122M-B1	
	SH122M-B2	
	SH122S-B1	
	SH122S-B2	
	SH122XL-B1	
	SH122XL-B2	
	SH122XS-B1	
	SH122XS-B2	

	SP110L	
	SP110S	
	SP110XL	
Accessories		
Elastic Extension Straps	SP111L	
	SP111S	
	SP111XL	

Photograph:



Hook & Loop Chest Belt



Universal Elastic Strap



Monoflex Chest Belt

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-13-2021

Place and Date of issue

Matthew Kosh, President, Bodypoint, Inc.