

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 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
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

Photograph:



Hook & Loop Chest Belt



Elastic Chest 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 ISO16840-15:2024, 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.