Bodypoint

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.**

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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
Calf Support Strap	SP102L	**8411801GMN0005FU**
	SP102M	
	SP102S	
	SP103L	
	SP103M	
	SP103S	
	BB216-22MM	
	BB218-22MM	
	BB220-22MM	

Photograph:

Calf Strap

Calf Panel

Shower Chair Calf Support

Intended purpose of the device: Used as a Postural Support Device (PSD) in a wheelchair to provide posterior calf support to help maintain a seated position.

Risk class and applicable rule in acc. with Annex VIII: Class I; applicable rule: 1

Common Specifications used: Conforms to ISO16840-15:2024, ISO10993-5:2009, REACH compliance

Additional information (if applicable): None

Matthew Kosh

Signature

Seattle, WA 2024-May-28

Place and Date of issue

Matthew Kosh, President, Bodypoint, Inc.