Bodypoint

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

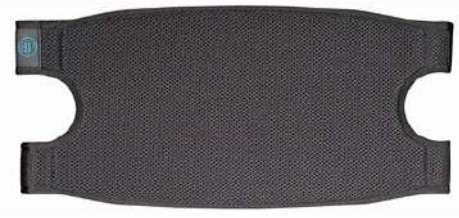
SRN (if assigned):

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
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 BS8625 and ISO16840-15 as a posterior lower leg support.

Additional information (if applicable): None

_____ _*Seattle, WA_ May-14-2021*_

Signature **Place and Date of issue**

Matthew Kosh, President, Bodypoint, Inc.