Bodypoint

D21-0411-01_revA

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

Authorised representative

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

Address: Kerkstraat 29, 7396PG Terwolde, Netherlands

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 (Note: The relevant regulations should be listed).

Product and trade name	Product Code(s)	Basic UDI-DI
Ankle Huggers	FT240L	**8411801GMN0006FW**
	FT240M	
	FT240S	
	FT240XL	
	FT240XS	
	FT240L	
	FT240M	
	FT240S	
Accessories		
Footman Loop	FT200AS-1	
Toe Straps, Velcro	FT221	

Photographs:

Intended purpose of the device:
This device is a flexible circumferential ankle support that wraps around the lower leg at the ankle, with straps extending downward that are anchored to footplates on wheelchairs, work chairs, bath chairs, or bicycles to stabilize the feet and hold them in position.

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

Common Specifications used: BS8625:2019, ISO16840-15, ISO7176-16, REACH Compliance

Signature

Seattle, WA_ June-7-2021

Place and Date of issue

Matthew Kosh, President, Bodypoint, Inc.