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.**

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 (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	

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: ISO16840-10:2021, ISO16840-15:2024, REACH Compliance

Matthew Kosh

Signature

Seattle, WA_ 2024-May-28

Place and Date of issue

Matthew Kosh, President, Bodypoint, Inc.