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

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SRN: US-MF-000042021

Authorised representative

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

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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
Evoflex Pelvic Positioning Support	EB205-L62 / -EBE	**8411801GMN0002FN**
	EB205-M46 / -EBE	
	EB225-L62 / -EBE	
	EB225-M46 / -EBE	
	EB235-S38 / -EBE	
	EB275-M46 / -EBE	
	EB275-S38 / -EBE	

Photograph:

Intended purpose of the device: Used in a wheelchair as a flexible pelvic positioning support belt 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 EN12183:2022, EN12184:2022, ISO16840-3:2022, ISO16840-10:2021, ISO16840-15:2024, ISO10993-5:2009, REACH compliance

Signature

Seattle, WA_ 2024-May-28

Place and Date of issue

Matthew Kosh, President, Bodypoint, Inc.