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

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
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	
Evoflex Belt Extender	EBE100	

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 and EN 12184, ISO16840-15, and BS8625 for pelvic positioning belts (anterior pelvic support)

Additional information (if applicable): None

Matthew Kosh

Signature

Seattle, WA_ April-25-2021

Place and Date of issue

Matthew Kosh, President, Bodypoint, Inc.