

Declaration of Conformity for class I devices According to MDR 2017/745, Annex IV

Manufacturer

Name: **Bodypoint, Inc.**

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Single Registration Numbers (SRN): **NL-AR-000017282**

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.

| 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), ISO10993-5, REACH compliance



Signature

Seattle, WA Dec-29-2021

Place and Date of issue

Matthew Kosh, President, Bodypoint, Inc.