

# Declaration of Conformity for class I devices

According to MDR 2017/745, Annex IV

## Manufacturer

Name: **Bodypoint, Inc.**

Address: 558 1<sup>st</sup> 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
Joystick Handle, 3" U-Shaped	PC101A/B	<b>8411801GMN0007FY</b>
Joystick Handle, 4" U-Shaped	PC102A/B	
Joystick Handle, 6" Flex-Shaft	PC104A/B	
Joystick Handle, Domed Rubber	PC107A/B	
Joystick Handle, Grooved Mushroom	PC110A/B	
Accessories		
Joystick Handle Display	BMR-27	
Joystick Collection Ring	BMR-45	

## **Photograph:**



**Intended  
of the device:**

**purpose**

A replacement ergonomic joystick handle shaped to fit the hand to improve driving control

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



Signature

Seattle, WA July-18-2021

Place and Date of issue

Matthew Kosh, President, Bodypoint, Inc.