

## 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

## **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	
Joystick Handle, 4" U-Shaped	PC102A/B	
Joystick Handle, 6" Flex-Shaft	PC104A/B	
Joystick Handle, Domed Rubber	PC107A/B	8411801GMN0007FY
Joystick Handle, Grooved Mushroom	PC110A/B	
Accessories		
Joystick Handle Display	BMR-27	
Joystick Collection Ring	BMR-45	

Photograph:







purpose

Intended

of the device:

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.