

# EC Declaration of Conformity

We hereby declare under our sole responsibility that the product group

Generic product group	03	<b>SpiroTrue</b> – Flow sensors for measuring air flow in breathing systems
Product subgroup	001	<b>H</b> - Differential pressure flow sensors

Product name	Product version	Product REF	UDI (GTIN-14)
SpiroTrue	H	1030132000	2 42516796 0156 6
Flow Sensor	H, 4310003	3030131005	2 42516796 0161 0
SpiroTrue	H (2m)	4030131003	2 42516796 0163 4
SpiroTrue	D (2,2m)	6030131002	2 42516796 0165 8
SpiroTrue	D (3,2m)	6030131001	2 42516796 0164 1

Complies with the essential requirements of Annex I and Annex II of the Council Directive 93/42/EEC as amended by 2007/47/EC concerning medical devices as well as the requirements of Regulation (EU) 2017/745, Article 120, Chapter (3).

In accordance with Annex IX of the Council Directive 93/42/EEC the product has been classified as Class IIa.

Application of the CE-marking:



MEDCERT GmbH, Pilatuspool 2, 20355 Hamburg

**Validity:**

**Date of expiry: 31 December 2021**

**Issuer:**

bluepoint medical GmbH & Co. KG  
An der Trave 15  
23923 Selmsdorf  
Germany

**Place, Date:**

Selmsdorf, 21. Mai 2021

**Legally binding signature:**

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Bernd Lindner  
General Manager