

# EC Declaration of Conformity

We hereby declare under our sole responsibility that the product group

Generic product group	03	<b>SpiroTrue – Flow sensors for measuring air flow in breathing systems</b>
Product subgroup	002	<b>A Hot-wire anemometric flow sensors</b>

Product name	Product version	Product REF	UDI (GTIN-14)
SpiroTrue	A	1030132006	2 42516796 0157 3
SpiroTrue	APC	3030131003	2 42516796 0159 7

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:



DNV MEDCERT GmbH, Pilatuspool 2, 20355 Hamburg

**Validity:**

**Date of expiry: 02 November 2023**

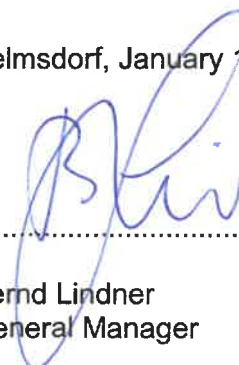
**Issuer:**

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

**Place, Date:**

Selmsdorf, January 1<sup>st</sup>, 2023

**Legally binding signature:**

  
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Bernd Lindner  
General Manager