

# 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	002	<b>A</b> Hot-wire anemometric flow sensors

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

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, Brooktorkai 18, 20457 Hamburg, Germany

**Validity:**

**Date of expiry: 31 December 2028**

**Issuer:**

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

**Place, Date:** Selmsdorf, 31 January 2026

**Legally binding signature:**



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Bernd Lindner  
General Manager