EC Declaration of Conformity

We hereby declare under our sole responsibility that the product group

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

Product name	Product version	Product REF	UDI (GTIN-14)
SpiroTrue	A	1030132006	2 42516796 0157 3
SpiroTrue	APC	3030131003	2 42516796 0159 7
Flow sensor	A, 4310001	3030131004	2 42516796 0160 3
Flow sensor	APC, 4310002	7030131001	2 42516796 0168 9
Flow sensor	AS432+	2030131000	2 42516796 0158 0
Flow sensor	AS432+AUTO	6030131004	2 42516796 0167 2

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:

CE 0482

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 1st, 2023

Legally binding signature:

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Bernd Lindner
General Manager