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	001	**H** - 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:

CE 0482

MEDCERT GmbH, Pilatuspool 2, 20355 Hamburg

Validity: **Date of expiry: 31 December 2022**

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

Place, Date: Selmsdorf, January 5th, 2022

Legally binding signature: .....

Bernd Lindner
General Manager