EC Declaration of Conformity

We hereby declare under our sole responsibility that the generic product group

SpiroTrue Flowsensor
Sensor for measuring air flow in breathing systems

REF	Type
1030132000	H
1030132006	A
2030131000	AS432+
3030131003	APC
3030131004	A, 4310001
3030131005	H, 4310003
4030131002	D
4030131003	H

REF	Type
6030131001	D
6030131002	D
6030131003	E
6030131004	AS432+AUTO
7030131001	APC, 4310002
10030131001	D
10030131002	D

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 2021**

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

Place, Date: Selmsdorf, 11 November 2019

Legally binding signature: .....

Bernd Lindner
General Manager