Vitalograph®
Your cardio-respiratory partner

Vitalograph (Ireland) Limited, Gort Road Business Park, Ennis, Co. Clare, V95 HFT4, Ireland.
Tel.: +353 (0)65 686 4100 Fax: +353 (0)65 682 9289 E-mail: sales@vitalograph.ie Web: www.vitalograph.ie

Declaration of Conformity

To the requirements of 93/42 EEC 169, volume 36, as amended

Vitalograph hereby ensures and declares that the following products and their accessories, bearing the CE Mark, meet the following provisions of the Directive:

- Class I devices comply with Annex VII per Article 11 Section 5. Devices classified as Class I, with a measuring function, comply with Annex V per Annex VII Section 5.
  CE certificate CE85553, first issue 07 July 2004;
- Class IIa devices meet the provisions of Annex II per Article 11, Section 3a.
  CE certificate CE00772, first issued 14 July 1995. Reference Annex IX rule 10 of 93/42/EEC.

Notified Body BSI NL (2797), traceable to original BSI UK (0086), issued the above mentioned certificates.

Model	Product name	GMDN	Class
2020	Mouthpiece	44545	I**
2024	SafeTway (incl Eco)	44545	IIa**
2030	Noseclip	10907	I**
2040	Precision Syringe	17250	I*
2120	Hand Held (in2itive)	13680	IIa
2150	Gold Standard	13680	IIa
2510	Emergency Aspirator	47368	I
2820	BVF (incl Eco)	61097	IIa**
2900	BreathCo	35467	I*
4000	Respiratory Monitor	46906	IIa
4300	Peak Flow Meter	46872	I*
4530	Inhaler Compliance	42629	I
4500	AIM	42629	I*
6000	Alpha	13680	IIa
6300	Micro	13680	IIa
6600	Compact	13680	IIa
6800	Pneumotrac	13680	IIa
7000	Spirotrac	13680	IIa
7100	VitaloJAK	62276	IIa
7100	VitaloJAK sensor	62276	I**
8400	Inhaler Trainer	-	I
8900	Vitalink	-	I

* Indicates Class I with a measuring function
** Indicates Accessory to one or more of these products

Vitalograph operates a Quality Management System that complies with the requirements of ISO 13485:2016 and EN ISO 13485:2016, for the design and manufacture of a range of medical diagnostic and therapeutic instruments, and holds certificate MD 82182.

Signed for and on behalf of Vitalograph:

(Signature)

Tony O'Hanlon, RA / QA Manager

March 27, 2019
(Date)