



VITALOGRAPH (IRELAND) LIMITED, GORT ROAD BUSINESS PARK, ENNIS, CO. CLARE.
TELEPHONE: +353 (0) 65 6864100 FAX: +353 (0) 65 6829289

Declaration of Conformity

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

Vitalograph hereby ensures and declares that the following Products & their Accessories, bearing the CE Mark, meet the following provisions of the Directive:

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

MODEL N ^o	PRODUCT NAME	GMDN	CLASS
2020	Mouthpiece	P44545	I**
2024	SafeTway	P44545	IIa**
2030	Noseclip	P10907	I**
2040	Precision Syringe	P17250	I*
2110	PEF/FEV Diary	P46906	IIa
2120	Hand Held	P13680	IIa
2130	Base Station Spirometer	P13680	IIa
2150	Gold Standard	P13680	IIa
2160	Gold Standard +	P13680	IIa
2900	BreathCo		I*
2200	ResusBag	P17591	IIa
2400	Resuscitation Kit	P36690	IIa
2410	Resuscitation Outfit	P36690	IIa
2510	Emergency Aspirator	P47368	I
2820	BVF	P44545	IIa*
4000	Respiratory Monitor	P46906	IIa
4300	Peak Flow Meter	P46872	I*
4530	Inhaler Compliance		I
4500	AIM	P42629	I*
6000	Alpha	P13680	IIa
6300	Micro	P46906	IIa
6600	Compact	P13680	IIa
6800	Pneumotrac	P13680	IIa
7000	Spirotrac	P13680	IIa
7100	VitaloJAK	P62276	IIa
7100	VitaloJAK sensor	P62276	I**
8400	Inhaler Trainer		I

* Indicates Class I with a measuring function.

** Indicates Accessory to one or more of these products

Date: 26 Oct 2016

Tom J Healy
Regulatory Affairs / QA Manager.