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, and manufactured at Vitalograph (Ireland) Ltd, Gort Road, Ennis, Co. Clare V95 HFT4, 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 BSI UK (0086) issued the above mentioned certificates.

Model	Product name	GMDN	Class
2020	Mouthpiece	44545	I*
2024	SafeTway (incl Eco)	44545	IIa*
2040	Precision Syringe	17250	IIa
2120	Hand Held (in2itive)	13680	IIa
2150	Gold Standard	13680	IIa
2900	BreathCo	35467	Im
4000	Respiratory Monitor	46906	IIa
4130	BT12 ECG	16231	IIa
4500	AIM	42629	Im
4530	Inhaler Adherence	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*

* Indicates Accessory to one or more 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

June 29, 2020

(Date)

16251-41 Declaration of Conformity

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, and manufactured at Shanghai Yaojia Medical Devices Company Ltd, No. 15, Lane 399, Zhenzhongxin Road, Xiaokunshan Town, Songjiang District, 201614 Shanghai, China, as a sub-contractor on behalf of Vitalograph (Ireland) Ltd, 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 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*
2820	BVF (incl Eco)	61097	IIa*
4300	Peak Flow Meter	46872	Im

* Indicates Accessory to one or more 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.

Shanghai Yaojia Medical, operates a Quality Management System that complies with the requirements of EN ISO 13485:2016, for the manufacture of these devices, and holds certificate SX 60110624 0001, issued by Notified Body, TUV Rheinland (0197).

Signed for and on behalf of Vitalograph:

(Signature)

Tony O'Hanlon, RA / QA Manager

June 29, 2020

(Date)

16251-41 Declaration of Conformity

Vitalograph (Ireland) Limited, Gort Road Business Park, Ennis, Co. Clare, V95 HFT4, Ireland.
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Declaration of Conformity

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

Vitalograph hereby ensures and declares that the following products, bearing the CE Mark, and manufactured at Plaxtron Industrial (Medical) Sdn. Bhd., Plot 28 Kawasan Perusahaan Jelapang II, Zon Perdagangan Bebas, Ipoh, Perwak, 30020, Malaysia, as a sub-contractor on behalf of Vitalograph (Ireland) Ltd, 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;

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

Model	Product name	GMDN	Class
4300	Peak Flow Meter	46872	Im

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.

Plaxtron Industrial, operates a Quality Management System that complies with the requirements of ISO 13485:2016 and NS EN ISO 13485:2016, for the manufacture of these devices, and holds certificate 246995-2017-AQ-RGC-NA-PS, issued by Notified Body, DNV GL Presafe AS (2460).

Signed for and on behalf of Vitalograph:

(Signature)

Tony O'Hanlon, RA / QA Manager

June 29, 2020

(Date)

16251-41 Declaration of Conformity

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, and manufactured at Ningbo Tianyi Medical Applicances Co. Ltd, No 788 Mozhi North Road, Tourism Resort, Dongqian Lake, Ningbo, 315121, China, as a sub-contractor on behalf of Vitalograph (Ireland) Ltd, meet the following provisions of the Directive:

- 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 BSI UK (0086) issued the above mentioned certificate.

Model	Product name	GMDN	Class
2820	BVF (incl Eco)	61097	IIa*

* Indicates Accessory to one or more 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.

Ningbo Tianyi, operates a Quality Management System that complies with the requirements of EN ISO 13485:2016, for the manufacture of these devices, and holds certificate Q5 18 05 59388 013, issued by Notified Body TUV SUD (0123).

Signed for and on behalf of Vitalograph:

(Signature)

Tony O'Hanlon, RA / QA Manager

June 29, 2020

(Date)

16251-41 Declaration of Conformity

Vitalograph (Ireland) Limited, Gort Road Business Park, Ennis, Co. Clare, V95 HFT4, Ireland.
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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, and manufactured at Suntop CN Co Ltd, Room 508, 509, Building B4, No 389 Zhaojiajing Road, Songjiang District, Shanghai, China, as a sub-contractor on behalf of Vitalograph (Ireland) Ltd, 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 BSI UK (0086) issued the above mentioned certificates.

Model	Product name	GMDN	Class
2020	Mouthpiece	44545	I*
2820	BVF (incl Eco)	61097	IIa*
4300	Peak Flow Meter	46872	Im

* Indicates Accessory to one or more 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.

Suntop CN Co Ltd, operates a Quality Management System that complies with the requirements of ISO 13485:2016, for the manufacture of these devices, and holds certificate QS 104284 0001, issued by Notified Body, TUV SUD (0123).

Signed for and on behalf of Vitalograph:

(Signature)

Tony O'Hanlon, RA / QA Manager

June 29, 2020

(Date)

16251-41 Declaration of Conformity