Vitalograph

A Global Leader in Respiratory Diagnostics

EU Declaration of Conformity

To the requirements of MDD 93/42 EEC, as amended /
To the requirements of MDR 2017/745, as amended

Vitalograph (SRN No IE-MF-000004858) hereby declares that the devices listed hereunder, with each bearing the CE Marking of conformity, and manufactured by Vitalograph (Ireland) Ltd, Gort Road, Ennis, Co. Clare V95 HFT4, Ireland, meet either the provisions of the Directive or the Regulation, as applicable to device. In addition, Vitalograph (Ireland) Ltd declare that irrespective of the sub-contracted manufacturer, the EU declaration of conformity is issued under the sole responsibility of Vitalograph as the legal manufacturer.

- **MDD**: Reference Annex IX of 93/42/EEC. Devices of Class I comply with Annex VII per Article 11 Section 5. Class Im, comply with Annex V per Annex VII Section 5. EC Certificate CE85553. Class IIa comply with Annex II, Article 11, Section 3a. EC Certificate CE00772.
- **MDR**: Devices of Class I comply with Annex II and III. Class Im comply with Annex IX Chapters I and III. EC Certificate <pending>. Class IIa comply with Annex IX Chapters I and III, EC certificate <pending>
- Classifications determined using; MDD Annex IX, or MDR Annex VIII.

Common Specifications used to demonstrate conformity: 60601, 10993, and 18562, both primary & collaterals

EC Certificates issued by Notified Body, BSI NL No 2797, traceable to original BSI UK No 0086

Model	Product name	GMDN	EMDN / CND	UMDNS	EU Class	MDD	MDR	GMN
2024	SafeTway	44545	Z12150185	41898	IIa**	Y	N	50991692024ST
2040	Precision Syringe	17250	Z12159080	17250	I	N	Y	50991692040SR
2120	Hand Held (in2itive)	13680	Z12159099	13680	IIa	Y	N	50991692120SQ
2150	Gold Standard	13680	Z12150101	13680	IIa	Y	N	50991692150SZ
2820	BVF	61097	R040101	11712	IIa**	Y	N	50991692820TT
4000	Respiratory Monitor	46906	Z12150102	34455	IIa	Y	N	50991694000ST
4130	BT12 ECG	16231	Z1203020280	11411	IIa	Y	N	50991694130T9
6000	Alpha	13680	Z12159099	13680	IIa	Y	N	50991696000T9
6300	Micro	13680	Z12159099	13680	IIa	Y	N	50991696300TQ
6600	Compact	13680	Z12159099	13680	IIa	Y	N	50991696600U7
6800	Pneumotrac	13680	Z12159099	13680	IIa	Y	N	50991696800UH
7000	Spirotrac	64339	Z12150182	26753	IIa	Y	N	50991697000TG
7100	VitaloJAK	62276	V9099	28280	IIa	Y	N	50991697100TM
9100	Pulmonary Function Test equipment	35282	Z12159003	26786	IIa	Y	N	50991699100U3

** Indicates medical device accessory to one or more Vitalograph products

Vitalograph operates a Quality Management System complying with requirements of ISO 13485:2016 & EN ISO 13485:2016 for the design, development, manufacture, and distribution of medical devices, holding certificate MD 82182.

(Signature)
Tony O'Hanlon, RA / QA Manager

June 03, 2022
At Vitalograph (Ireland) Ltd, Gort Road Business Park, Ennis, Co. Clare, V95 HFT4, Ireland, on this date

This Declaration applies to all devices hereon at date of signature. It expires for those devices under MDD on 25 May 2024, unless rev updated, while for those under MDR, Declaration remains valid until such time as it is rev updated or withdrawn.

Vitalograph (Ireland) Ltd.
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F J Keane | K J Moore | H E Venn (UK)

Company Registration Number:
48600

vitalograph.com

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To the requirements of MDR 2017/745, as amended

Vitalograph (SRN No IE-MF-000004858) hereby declares that the devices listed hereunder, with each bearing the CE Marking of conformity, 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 either the provisions of the Directive or the Regulation, as applicable to device. In addition, Vitalograph (Ireland) Ltd declare that irrespective of the sub-contracted manufacturer, the EU declaration of conformity is issued under the sole responsibility of Vitalograph as the legal manufacturer.

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Model	Product name	GMDN	EMDN/CND	UMDNS	EU Class	MDD	MDR	GMN
2020	Mouthpiece	44545	R9099	41898	I	N	Y	50991692020SK
2024	SafeTway	44545	Z12150185	41898	IIa**	Y	N	50991692024ST
2030	Noseclip	10907	R9099	10907	I	N	Y	50991692030SN
2820	BVF	61097	R040101	11712	IIa**	Y	N	50991692820TT
4300	Peak Flow Meter	65366	Z12150102	15965	Im	Y	N	50991694300TA

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(Signature)
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To the requirements of MDR 2017/745, as amended

Vitalograph (SRN No IE-MF-000004858) hereby declares that the devices listed hereunder, with each bearing the CE Marking of conformity, 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 to Vitalograph (Ireland) Ltd, meet either the provisions of the Directive or the Regulation, as applicable to device. In addition, Vitalograph (Ireland) Ltd declare that irrespective of the sub-contracted manufacturer, the EU declaration of conformity is issued under the sole responsibility of Vitalograph as the legal manufacturer.

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Common Specifications used to demonstrate conformity: 60601, 10993, and 18562, both primary & collaterals

EC Certificates issued by Notified Body, BSI NL No 2797, traceable to original BSI UK No 0086

Model	Product name	GMDN	EMDN/CND	UMDNS	EU Class	MDD	MDR	GMN
4300	Peak Flow Meter	65366	Z12150102	15965	Im	Y	N	50991694300TA

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Vitalograph (SRN No IE-MF-000004858) hereby declares that the devices listed hereunder, with each bearing the CE Marking of conformity, and manufactured at Ninbo Tianyi Medical Appliances Co. Ltd, No 788 Mozhi North Road, Tourism Resort, Dongqian Lake, Ningbo, 315121, China, as a sub-contractor to Vitalograph (Ireland) Ltd, meet either the provisions of the Directive or the Regulation, as applicable to device. In addition, Vitalograph (Ireland) Ltd declare that irrespective of the sub-contracted manufacturer, the EU declaration of conformity is issued under the sole responsibility of Vitalograph as the legal manufacturer.

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Model	Product name	GMDN	EMDN/CND	UMDNS	EU Class	MDD	MDR	GMN
2820	BVF	61097	R040101	11712	IIa**	Y	N	50991692820TT

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Vitalograph (SRN No IE-MF-000004858) hereby declares that the devices listed hereunder, with each bearing the CE Marking of conformity, and manufactured at Suntop CN Co. Ltd, Room 508, 509, Building B4, No 389 Zhaojiajing Road, Songjiang District, Shanghai, China, as a sub-contractor to Vitalograph (Ireland) Ltd, meet either the provisions of the Directive or the Regulation, as applicable to device. In addition, Vitalograph (Ireland) Ltd declare that irrespective of the sub-contracted manufacturer, the EU declaration of conformity is issued under the sole responsibility of Vitalograph as the legal manufacturer.

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