11. DECLARATION OF CONFORMITY

Product: *4000 Respiratory Monitor asma-1*

Vitalograph hereby ensures and declares that the above product associated with this user manual, is designed and manufactured in accordance with the following QMS regulations and standards:

- European Medical Devices Directive {MDD} 93/42/EEC.
- This device, classified as 2a as per Annex IX of MDD 93/42/EEC, meets the following provisions of Annex II of the Medical Devices Directive as per Article 11, section 3a, excluding point 4 of Annex II.

CE 0086

- This device complies with the EMC Directive 89/336/EC, conformance demonstrated by following standard EN60601-1-2:2001. Equipment classification: Residential.

Canadian Medical Device Regulation {CMDR}

FDA Quality System Regulation {QSR} 21 CFR 820.

EN ISO 13485: 2003. Medical devices. Quality management systems. Requirements for regulatory purposes.

Certifying Body {for 93/42/EEC and CMDR}: British Standards Institute {BSI}

Certificate Nos. CE 00772, MD 82182, FM 83550

Signed on behalf of Vitalograph (Ireland) Ltd.

B. R. Garbe.

Group Managing Director