



TY VERLON INDUSTRIAL ESTATE, BARRY, SOUTH GLAMORGAN, CF63 2BE, WALES, UNITED KINGDOM

Declaration of Conformity

LION/DOC/42020-2/2012

Manufacturer: Lion Laboratories Ltd

Address: Ty Verlon Industrial Estate
Barry
CF63 2BE

Product Type: Breath Alcohol Instrument

Model: Lion AlcoBlow[®] (PA42020)

The manufacturer declares that the product listed above conforms to the requirements of the Medical Devices Directive 93/42/EEC, amended by 2007/47/EC, as a Class I device.

Harmonised standards applied during the design, and the construction of the Technical File are:-

BS EN 60601-1:2006 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

BS EN 60601-1-2:2007: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

BS EN 60601-1-6:2010 General requirements for basic safety and essential performance – Collateral standard: Usability

BS EN 60601-1-8:2007 General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

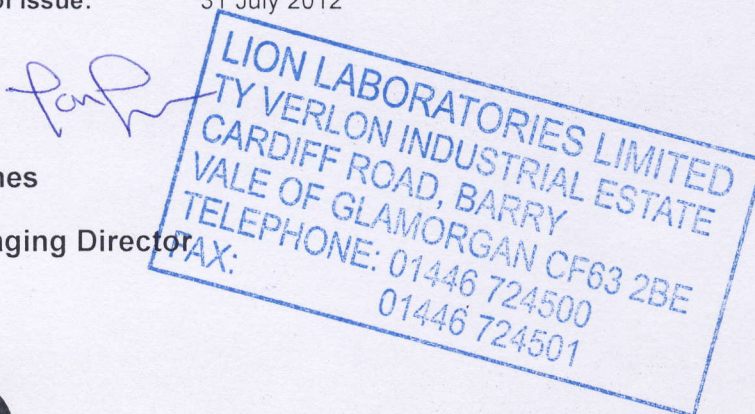
BS EN ISO 14971:2007 Medical devices – Application of risk management to medical devices

I, the undersigned, representing the manufacturer, declare in sole responsibility, that the product specified above, to which this declaration relates, conforms to the requirements of the above mentioned directives and standards.

Date of Issue: 31 July 2012

I. Jones

Managing Director



FM25502
ISO9001

Lion Laboratories Limited

Reg. Office of Lion Laboratories Limited: As Address above Reg. No: 1591869 England and Wales

