



EC Certificate Production Quality Assurance System: Certificate GB19/964824

The management system of

Clement Clarke International Ltd

Edinburgh Way, Harlow, Essex, CM20 2TT, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

- Nebulising System Tubing sets:**
Aerosol Masks, Micro-Neb Mask Kits, Mouthpiece Kit, Nebulisers,
Inline Adaptor Kit and Year Packs.
- Medium Concentration Oxygen Device sets:**
Duo Masks, Securi Tube, Clear View Masks and Tubing.
- Controlled Oxygen Device sets:**
Tru Flow Masks, Tru Flow Plug in Venturi, Tru Flow Recovery T Piece.

Annex V Metrological Aspects Only - Restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements
Peak flow meters

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 16 December 2019 until 03 February 2024
and remains valid subject to satisfactory surveillance audits
Issue 1. Certified since 13 March 1995
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered GB/PC/ 04298

Authorised by

SGS Belgium NV, Notified Body 1639

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