EC Certificate Production Quality Assurance System: Certificate
GB12/87147

SGS

The management system of

Clement Clarke International Ltd

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

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 03 February 2013 until 03 February 2018 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 03 February 2016 Issue 2. Certified since 13 March 1995

Certification is based on reports numbered GB/PC 04298

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 13 0311 M2

Page 1 of 2







EC Certificate Production Quality Assurance System: Certificate GB12/87147, continued

Clement Clarke International Ltd

Directive 93/42/EEC

on medical devices, Annex V

Issue 2

Detailed scope

Annex V

Nebuliser kits, nebuliser and oxygen therapy including venturi masks and accessories including paediatric masks, hot and cold humidifiers, nasal cannula, nasal masks, EMS ventilator circuits, peep valves, manual resuscitators, laryngoscope and guedal airways.

Annex V Metrological aspects only – Restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements

Peak flow meters.

For placing on the market of Class IIb or Class III devices covered by this certificate, an EC Type

Examination Certificate according to Annex III is required.