EC Certificate Production Quality Assurance System: Certificate GB09/76992

The management system of

PROACT Medical Ltd

9 - 13 Oakley Hay Lodge, Great Folds Road, Oakley Hay Business Park,
Corby, Northamptonshire, NN18 9AS, 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 27 July 2015 until 05 March 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 11 February 2018
Issue 7. Certified since 05 March 2009

Certification is based on reports numbered GB/PC 220242

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
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SGS CE 14 0315 M2

PROACT Medical Ltd

Directive 93/42/EEC

on medical devices, Annex V

Issue 7

Detailed scope

Annex V Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.

Intubating Stylets, Nasopharyngeal Airways, Suction Catheters and Oropharyngeal Airways.

Annex V

Sterile Devices:

Laryngeal Airways, Endotracheal Tubes, Endotracheal Tube Introducers, Endobronchial Tubes, Tracheostomy Tubes, Yankauer Handles and Suction Tubing, Endobronchial Blockers,

Non-Sterile Devices:

Aerosol Masks, Oxygen Masks, Nebulizer Kits, Manual Resuscitators, Nasal Cannulae, Anaesthesia Masks.

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.