EC Certificate Production Quality Assurance System: Certificate GB11/83991

The management system of

Prima Medical Ltd

Mill 16, Bath Road Trading Estate, Lightpill, Stroud, Gloucestershire, GL5 3QF, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

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

For the following products

Sterile single use electrosurgery fingerswitches (without integral electrodes). Sterile single use monopolar & bipolar cables. Sterile electrosurgical dispersive pad. Sterile Quivers.

This certificate is valid from 28 September 2012 until 28 September 2017 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 28 September 2015

Issue 2. Certified since 21 June 2004

Certification is based on reports numbered GB/PC 209781

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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SGS CE 18 0811

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EC Certificate Full Quality Assurance System: Certificate GB04/62137

The management system of

Prima Medical Ltd

Mill 16, Bath Road Trading Estate, Lightpill, Stroud, Gloucestershire, GL5 3QF, UK has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Single use & re-usable electrosurgery fingerswitches with integral electrodes. Reusable and single use electrodes. Reusable bi-polar, mono-polar & non stick forceps. Orthopaedic suction units. Sterile electrode cleaning pads, Sterile single use & re-usable microdissection needle electrodes.

For placing on the market of Class III devices covered by this certificate, an EC Design Examination

Certificate according to Annex II (Section 4) is required.

This certificate is valid from 28 September 2012 until 28 September 2017 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 28 September 2015 Issue 11. Certified since 21 June 2004

Certification is based on reports numbered GB/PC 209781

Authorised by



SGS United Kingdom Ltd, Notified Body 0120

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