

# SGS

Certificate GB04/62138

The management system of

## Prima Medical Ltd

Unit 21 Daniels Industrial Estate, Bath Road,  
Stroud, Gloucestershire, GL5 3TJ, UK

has been assessed and certified as meeting the requirements of

### ISO 13485:2003

For the following activities

**Manufacture and supply of re-usable and sterile single use electrosurgery fingerswitches, foot controlled handles, electrodes, bi-polar and mono-polar forceps, re-usable connecting dispersive plate cables, bi-polar and mono-polar cables, footswitches and orthopaedic suction units, manual vacuum aspirator (MVA).**

This certificate is valid from 14 November 2009 until 28 September 2012 and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 28 September 2012  
Issue 5. Certified since 21 June 2004

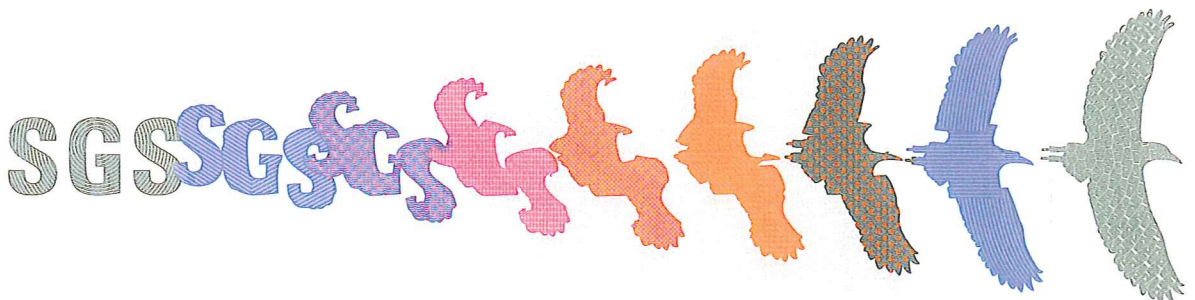
Authorised by



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SGS 13485-2 0308

Page 1 of 1



## Prima Medical Ltd

### Directive 93/42/EEC

Annex II (excluding Section 4) and  
Annex V (sterility aspects only)

Issue 8

Detailed scope

#### Annex II (excluding Section 4)

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 brushes (acetabular). Sterile electrode cleaning pads, Sterile single use & re-usable micro-dissection needle electrodes.

#### Annex V (sterility aspects only)

Sterile single use electrosurgery fingerswitches (without integral electrodes) and sterile foot controlled handles. Sterile brushes (femoral). Sterile single use monopolar & bipolar cables. Sterile electro-surgical dispersive pad.

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Certificate GB04/62137

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has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC

Annex II (excluding Section 4) and  
Annex V (sterility aspects only)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 14 November 2009 until 28 September 2012  
and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 28 September 2012  
Issue 8. Certified since 21 June 2004

Notified Body Number 0120

This is a multi-site certification.  
Additional site details are listed on the subsequent page.

Authorised by

CE  
0120

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SGS CE 01 0308 M2

Page 1 of 2

