

The management system of

## Mediplus Ltd

Unit 7, The Gateway Centre, Coronation Road, Cressex Business Park,  
High Wycombe, Bucks, HP12 3SU, UK

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 19 December 2006 until 19 June 2010 and  
remains valid subject to satisfactory surveillance audits.  
Issue 12. Certified since 18 April 1997

Notified Body Number 0120

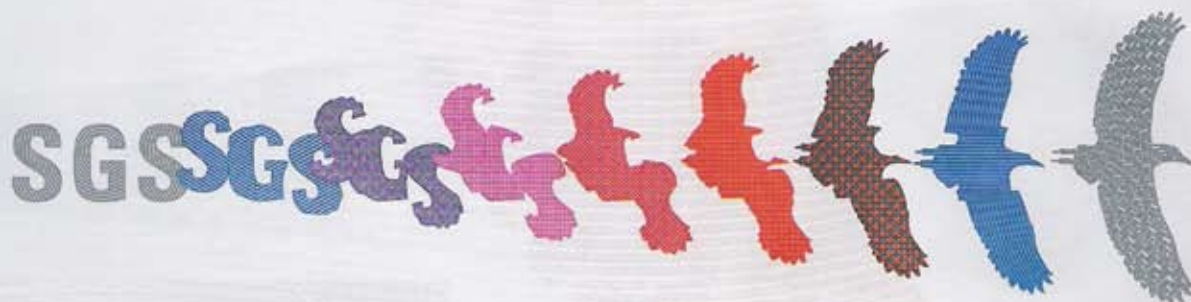
Authorised by

**CE**  
**0120**

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SGS CE 01 0107 M2

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## **Mediplus Ltd**

### **Directive 93/42/EEC**

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

Issue 12

Detailed scope

#### **Annex II (excluding Section 4):**

**Sterile and non-sterile rectal catheters; sterile bladder catheters; sterile urology administration sets; sterile gastro-intestinal manometry catheters; non-sterile, single-use and reusable gastro-intestinal manometry catheters and extension sets; non-sterile single-use and reusable pH catheters for clinical measurement in gastroenterology; sterile anaesthetic sets; sterile breast lesion location sets; sterile vascular ligation/occlusion loops; sterile biopsy needles and sterile suture supports. Biliary Stents and Biliary Stent Kits. Gastro-intestinal pump transducers. Non-invasive bladder pressure measuring device.**

#### **Annex V (sterility aspects only):**

**Meatal dilator.**

**CE  
0120**

Certificate GB97/9734

**SGS**

The management system of

## Mediplus Ltd

Unit 7, The Gateway Centre, Coronation Road, Cressex Business Park,  
High Wycombe, Bucks, HP12 3SU, UK



has been assessed and certified as meeting the requirements of

## ISO 9001:2000

For the following activities

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

Further clarifications regarding the scope of this certificate and the applicability of  
ISO 9001:2000 requirements may be obtained by consulting the organisation

This certificate is valid from 19 December 2006 until 19 December 2009  
Issue 8. Certified since 18 April 1997

Authorised by

*P. Earl*

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SGS 9001-2 01 0303 M2

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# Mediplus Ltd

## ISO 9001:2000



Issue 8

Detailed scope

**The design, development and manufacture of sterile devices:  
anaesthesia systems, biliary stents, catheters, irrigation and drainage  
systems, meatal dilator, vascular ligation occlusion loops,  
suture support and needles.**

**The design, development and manufacture of non-sterile devices:  
catheters, CystoAid (urine collection device), cuffs, pressure  
transducers and drainage systems.**

**The design, development, manufacture, installation and service of  
non-sterile bladder pressure measuring devices.**

**The supply and stockholding of private label medical devices.**

**For use in anaesthesiology, urology, obstetrics and gynaecology,  
geriatrics, sexual health, gastroenterology, theatres, breast screening  
and surgery.**

Further Clarifications regarding the scope of this certificate and the applicability of  
ISO 9001:2000 requirements may be obtained by consulting the organisation



Certificate GB97/9735

SGS

The management system of

## Mediplus Ltd

Unit 7, The Gateway Centre, Coronation Road, Cressex Business Park,  
High Wycombe, Bucks, HP12 3SU, UK



has been assessed and certified as meeting the requirements of

## ISO 13485:2003

For the following activities

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

This certificate is valid from 19 December 2006 until 19 June 2010 and  
remains valid subject to satisfactory surveillance audits.  
Issue 10. Certified since 18 April 1997  
Recertification Audit due 19 December 2009

Authorised by

*P. Earl*

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SGS 13485-2 0107 M2

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**Mediplus Ltd**  
**ISO 13485:2003**



Issue 10

Detailed scope

The design, development and manufacture of sterile devices: anaesthesia systems, biliary stents, catheters, irrigation and drainage systems, meatal dilator, vascular ligation occlusion loops, suture support and needles.

The design, development and manufacture of non-sterile devices: catheters, CystoAid (urine collection device), cuffs, pressure transducers and drainage systems.

The design, development, manufacture, installation and service of non-sterile bladder pressure measuring devices.

The supply and stockholding of private label medical devices.

For use in anaesthesiology, urology, obstetrics and gynaecology, geriatrics, sexual health, gastroenterology, theatres, breast screening and surgery.

