

# UL International (UK) Ltd

An affiliate of Underwriters Laboratories Inc.

## EC Certificate - Production Quality Assurance System Approval Certificate

(Annex V section 3 of the Directive 93/42/EEC on Medical Devices)

### Manufacturer

Mediwatch (UK) Ltd  
Lumonics House  
Valley Drive  
Rugby CV21 1TQ  
United Kingdom

### Authorised Representative

Not Applicable

**Scope of Certificate:** Supply of extension and perfusion sets, water-filled catheters and infusion sets for pump.

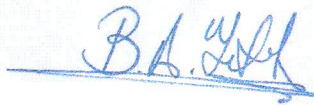
**Device Classifications:** Class IIa

**Device Descriptions:** Extension and Perfusion Sets  
Water-filled Catheters  
Infusion Sets for Pump

**Model/Type :** Please refer to Attachment 1 & 2 for product codes

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex V of the Directive 93/42/EEC on Medical Devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Certificate issued by:



**Certification Manager**

For UL International (UK) Ltd

UL International (UK) Ltd  
Wonersh House  
The Guildway  
Old Portsmouth Road  
Guildford, Surrey GU3 1LR  
United Kingdom  
+44 (0)1483 302130

Certificate no: 624  
Original certificate: 12 May 2010  
Current certificate: 14 September 2010  
Certificate expiry: 18 May 2011

Notified Body No.

**0843**

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## Attachment 1

The products detailed in the certificate below includes the following:

### Products

### Classification

#### **Catheters:**

9021P090x	Bladder Pressure Catheter, 4.5F, 2.600 mm	Class IIa
9021P091x	2-lumen Catheter for Cystometry, 8F, 2.600 mm	Class IIa
9021P092x	2-lumen Catheter for Cystometry, 6F, 2.600 mm	Class IIa
9021P106x	1-lumen Catheter for UPP, 8F	Class IIa
9021P109x	1-lumen Catheter for Rectal Pressure, 8F	Class IIa
9021P121x	1-lumen Catheter for Bladder Pressure, 5F	Class IIa
9021P445x	Rectal Flap Catheter, 4.5F, 2.600 mm	Class IIa
9021P446x	Rectal Split Balloon Catheter, 4.5F, 2.600 mm	Class IIa
9021P447x	Rectal Split Balloon Catheter with Introducer, 4.5F, 2.600 mm	Class IIa
9021P448x	Rectal Flap Catheter with Introducer, 4.5F, 2.600 mm	Class IIa
9021P521x	Bladder Filling Catheter, 6F, 400 mm	Class IIa
9021P522x	Bladder Filling Catheter, 8F, 400 mm	Class IIa
9021P523x	Bladder Filling Catheter, 10F, 400 mm	Class IIa
9021P634x	Extension Line, 2.000 mm	Class IIa

#### **Pump Sets:**

9021O118x	Pump Tube Set for Laborie Systems	Class IIa
9021O119x	Pump Tube Set for Sedia Systems	Class IIa
9021O120x	Pump Tube Set for Albyn Systems	Class IIa

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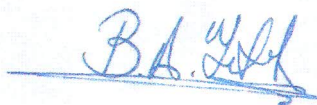
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## Attachment 2

The products detailed in the certificate below includes the following:

<u>Products</u>		<u>Classification</u>
9021O122x	Pump Tube Set for MMS Libra and Solar Systems	Class IIa
9021O123x	Pump Tube Set for MMS UD2000 Systems	Class IIa
9021O129x	Pump Guard	Class IIa
<b>Cystometry Packs:</b>		
9021T100x	2-lumen Cystometry Pack with Rectal Split Balloon, 8F	Class IIa
9021T101x	Cystometry Pack with Rectal Split Balloon, 8F	Class IIa
9021T102x	Cystometry Pack with Rectal Split Balloon with Introducer, 8F	Class IIa
9021T103x	Cystometry Pack with Rectal Flap, 8F	Class IIa
9021T104x	Cystometry Pack with Rectal Split Balloon, 6F	Class IIa
9021T105x	Cystometry Pack with Rectal Split Balloon with Introducer, 6F	Class IIa
9021T106x	Cystometry Pack with Rectal Flap, 6F	Class IIa
9021T107x	2-lumen Cystometry Pack with Rectal Split Balloon, 6F	Class IIa
9021T108x	Cystometry Pack with Rectal Split Balloon with Introducer, 10F	Class IIa
9021T109x	2-lumen Cystometry Pack with Rectal Split Balloon, 6F	Class IIa
9021T110x	2-lumen Cystometry Pack with Rectal Split Balloon, 8F	Class IIa

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