

UL International (UK) Ltd

An affiliate of Underwriters Laboratories Inc.

EC Certificate - Full Quality Assurance System Approval Certificate

(Annex II, 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: Design and Manufacture of ultrasound scanners and urological devices


Device Classifications: Class IIa

Device Descriptions: Ultrasound scanners and urological devices

Model/Type : See Attachment 1

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

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: 491
Original certificate: 13 November 2006
Current certificate: 14 September 2010
Certificate expiry: 12 November 2012

Notified Body No.

0843

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Attachment 1

The products detailed in the certificate below includes the following:

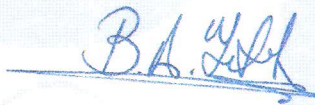
Products

Portascan Ultrasonic Bladder Scanner including Ultrasound probe
Bardscan including Ultra-Sound probe
Portascan+ Ultrasonic Bladder Scanner including Ultrasound probe
Bardscan II including Ultrasound probe
Multiscan including Ultrasound probes
Duet Encompass
Duet Logic G2
Urodynamic System Clinic G3
Urodynamic System Portable G3

Classification

Annex II, Class IIa
Annex II, Class IIa
Annex II, Class IIa
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