

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
Swift House
Cosford Lane,
Swift Valley Industrial Estate
Rugby
Warwickshire CV21 1QN
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: 05 November 2009
Certificate expiry: 12 November 2012



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Attachment 1

The products detailed in the certificate below includes the following:

Products

Classification

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

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