

ISO 9001

Buffalo Filter

595 Commerce Drive
Buffalo, NY 14228

Underwriters Laboratories Inc.® (UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with

ISO 9001:2000

EN ISO 9001:2000; BS EN ISO 9001:2000; ANSI/ASQ Q9001:2000

for the following scope of registration

3845 (US) : Electromedical and Electrotherapeutic Apparatus

The design and manufacture of medical, surgical and laparoscopic devices and accessories, tubing and hose for control of smoke evacuation.

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

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of Underwriters Laboratories Inc. ®.

File Number: A12634

Volume: 1 of 2

Original Certification Date: May 19, 2004

ISO 9001:2000 Issue Date: May 19, 2004

Revision Date: February 10, 2005

Renewal Date: May 18, 2007



S. Joe Bhatia
Executive Vice President, International



Buffalo Filter

595 Commerce Drive
Buffalo, NY 14228

Underwriters Laboratories Inc.® (UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with

ISO 13485:2003

CEN EN ISO 13485:2003 and EN ISO 13485:2003

for the following scope of registration

3845 (US) : Electromedical and Electrotherapeutic Apparatus

The design and manufacture of medical, surgical and laparoscopic devices and accessories, tubing and hose for control of smoke evacuation.

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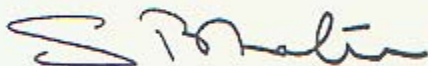
Volume: 2 of 2

Original Certification Date: May 19, 2004

ISO 13485:2003 Issue Date: February 10, 2005

Revision Date: February 10, 2005

Renewal Date: February 9, 2008



S. Joe Bhatia
Executive Vice President, International



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

Buffalo Filter, division of MEDTEK Devices, Inc
595 Commerce Drive
Buffalo
New York
14228
USA

Authorised Representative

Emergo Europe
Molenstraat 15
2513 BH
The Hague
The Netherlands

Model / type:

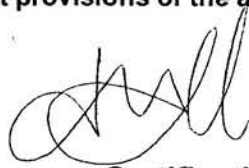
PenAdapt™ family of products for the removal of smoke, and casual fluid during electro-surgery and laser procedures.

Scope of quality system:

Manufacture of sterile hose, tube, adaptors and filters

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.
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United Kingdom
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Report no: 03UKM0645 and
04UKM1930
Certificate no: 360
Original certificate: 24 July 2004
Certificate expiry: 24 July 2007

