

Buffalo Filter, Div of Medtek Devices Inc.

595 Commerce Drive
Buffalo, NY 14228
United States



With an additional site location at:
155 Pineview
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

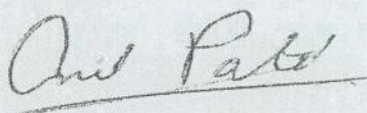
ISO 9001:2008

EN ISO 9001:2008; ANSI/ISO/ASQ Q9001-2008; CAN/CSA-ISO 9001-08

The design and manufacture of smoke evacuation systems, filters, and sterile hoses and tubing for the control of surgical smoke evacuation.

The additional site at 155 Pineview, Buffalo, NY performs: Design, servicing, purchasing, receiving, raw material inventory, calibration.

File Number: A12634
Certificate Number: 10NK02876.PDSX
Effective Date: May 19, 2010
Expiry Date: May 18, 2013



Anil N. Patel
General Manager, UL Health Sciences

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 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.



the standard in safety

Underwriters
Laboratories

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Buffalo, NY 14228
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CAN/CSA ISO 13485:2003

EN ISO 13485:2003 and ANSI/AAMI/ISO 13485:2003

The design, manufacture, and servicing of surgical exhaust extraction systems for the area of general surgery.

The additional site at 155 Pineview, Buffalo, NY performs: Design, servicing, purchasing, receiving, raw material inventory, calibration.

File Number: A12634
Certificate Number: 10NK02876.AZBA
Effective Date: May 19, 2010
Expiry Date: May 18, 2013



Anil N. Patel
General Manager, UL Health Sciences

UL is a CMDCAS Recognized Registrar

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.

Certificate of Registration

Underwriters Laboratories Inc.
333 Pfingsten Road
Northbrook, IL 60062 USA

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
Suite 100
595 Commerce Drive
Buffalo, NY 14228
USA

Authorised Representative

Emergo Europe
Molenstraat 15
NL-2513 BH
The Hague
The Netherlands

Scope of Certificate: Manufacture of sterile hose, tube, adaptors and filters

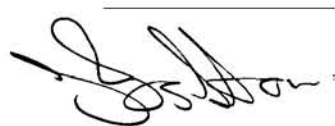
Device Classifications: Class I Sterile
Class IIa

Device Descriptions: Sterile and non-sterile smoke evacuation, filtration devices and associated tubes and hoses

Model/Type : Please refer to Attachment 1

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: 360
Original certificate: 24 July 2004
Current certificate: 18 June 2007
Certificate expiry: 18 June 2010



UL International (UK) Ltd

An affiliate of Underwriters Laboratories Inc.

Attachment 1

The products detailed in the certificate below includes the following:

<u>Products</u>	<u>Classification</u>
PenAdapt™ family of products for the removal of smoke, and casual fluid during electro-surgery and laser procedure, sterile and non-sterile.	Class IIa
LapEvac® family of products, sterile and non-sterile filtration devices.	Class IIa
Tubing, Hoses and Filter Accessories, sterile and non-sterile.	Class I Sterile

Certificate issued by:



Certification Manager
For UL International (UK) Ltd

UL International (UK) Ltd
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The Guildway
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