

Certificate US13/82781

The management system of

Buffalo Filter, division of MEDTEK Devices, Inc

5900 Genesee Street,
Lancaster, NY, 14086, United States



has been assessed and certified as meeting the requirements of

ISO 13485:2003 EN ISO 13485:2012

For the following activities

Design, manufacture, distribution, and servicing of smoke evacuation systems, including both sterile and non-sterile versions of filters, tubing, hoses, electrosurgical instruments and associated accessories for the control of surgical smoke evacuation.

This certificate is valid from 18 May 2013 until 18 May 2016
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 18 May 2016
Issue 2. Certified since 19 May 2010

Authorised by

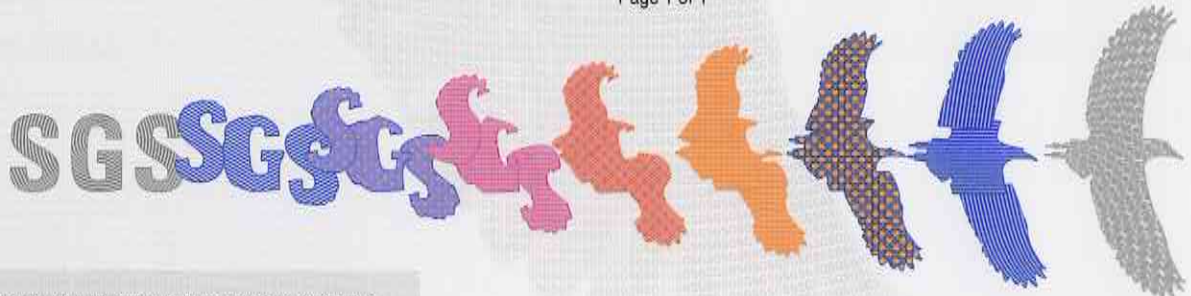
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SGS 13485-2 0612

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Certificate US13/82782

The management system of

Buffalo Filter, division of MEDTEK Devices, Inc

5900 Genesee Street,
Lancaster, NY, 14086, United States

has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

Design, manufacture, distribution, and servicing of smoke evacuation systems, including both sterile and non-sterile versions of filters, tubing, hoses, electrosurgical instruments and associated accessories for the control of surgical smoke evacuation.


Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 18 May 2013 until 18 May 2016 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 18 May 2016

Issue 2. Certified since 19 May 2010

Authorised by



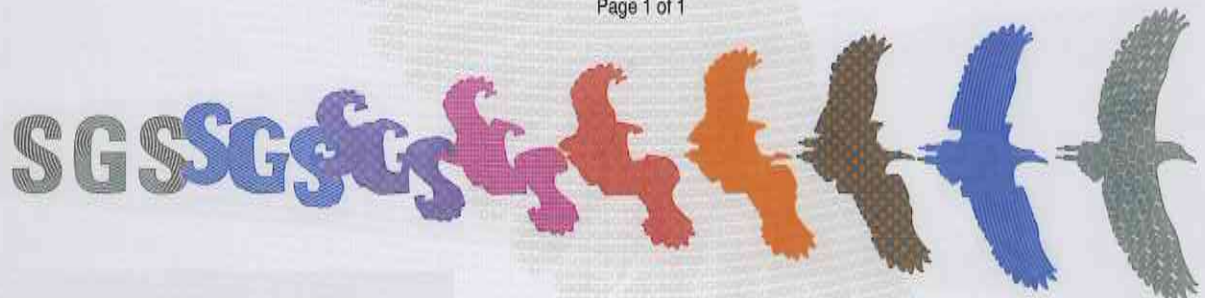
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EC Certificate Production Quality Assurance System: Certificate
US13/82779

SGS

The management system of

Buffalo Filter, division of MEDTEK Devices, Inc

5900 Genesee Street,
Lancaster, NY, 14086, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex V

For the following products

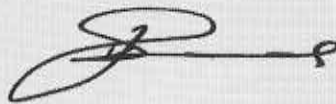
**Sterile electrosurgical instruments, incorporating smoke evacuation
for the control of surgical smoke plume.**

For placing on the market of Class IIb or Class III devices covered by this certificate, an EC Type
Examination Certificate according to Annex III is required.

This certificate is valid from 18 May 2013 until 18 May 2018
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 18 May 2016
Issue 2. Certified since 8 June 2010

Certification is based on reports numbered WW/PCI 604561

Authorised by

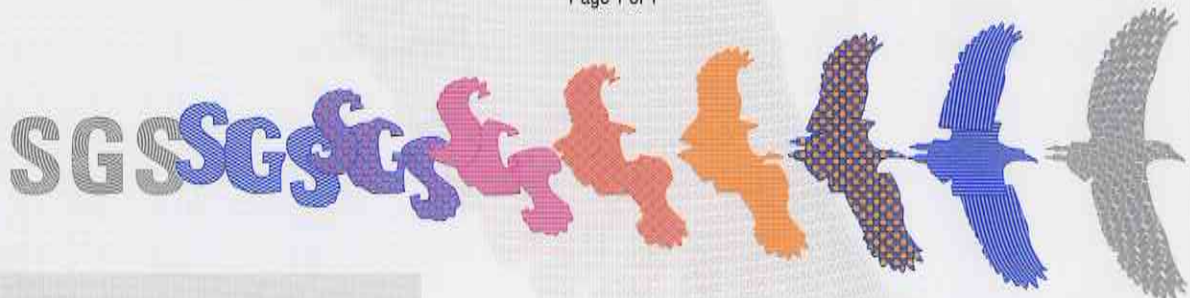


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Buffalo Filter, division of MEDTEK Devices, Inc

5900 Genesee Street,
Lancaster, NY, 14086, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

Restricted to the aspects of manufacture concerned with securing and
maintaining sterile conditions.

For the following products

**Sterile hoses, tubes, filters, for the control of surgical smoke
evacuation.**

This certificate is valid from 18 May 2013 until 18 May 2018
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 18 May 2016

Issue 1. Certified since 8 June 2010

Certification is based on reports numbered WW/PCI 604561

Authorised by

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