



World leader in surgical smoke evacuation™

5900 Genesee Street  
 Lancaster, New York 14086  
 (800) 343.2324 Domestic  
 (716) 835.7000 International  
 (716) 835.3414 Fax  
 www.buffalofilter.com  
 email to:  
 smoke-info@buffalofilter.com

## Declaration of Conformity

### PRODUCT IDENTIFICATION

| Product name  | Model/number                                 |
|---|--|
| Plume Safe Whisper Turbo AS<br>ViroVac<br>VisiClear | PSWTurbo AS 220<br>VV220<br>CTVV220<br>VC220 |

### MANUFACTURER

| Name of company     | Address                                    | Representative  |
|---------------------|--|---|
| Buffalo Filter, LLC | 5900 Genesee Street<br>Lancaster, NY 14086 | Greg Pepe, Vice President -<br>New Product Development,<br>Engineering, and Quality |

### AUTHORIZED REPRESENTATIVE

| Name of company | Address  | Telephone/email   |
|-----------------|--|---|
| Emergo Europe   | Molenstraat 15<br>2513 BH<br>The Hague,<br>The Netherlands | +31.70.345.8570 - phone<br>+31.70.346.7299 - fax<br>service@emergogroup.com |

### REGISTRATION INFORMATION

| Notified Body and ID #   | CE certificate number |
|--|-----------------------|
| SGS United Kingdom, Ltd.<br>202B Worle Parkway<br>Weston-super-Mare<br>BS22 6WA UK<br>ID# 0120 | Self certified        |

### CONFORMITY ASSESSMENT

| Device classification  | Route to compliance                                | Other Standards applied  |
|--|--|--|
| Class I, Short Term<br>Non-Invasive, Rule 1 and<br>Active, Rule 12 | Annex VII of MDD<br>93/42/EEC Council<br>Directive | EN ISO 13485:2012<br>QMS Medical Devices<br>EN ISO 14971:2012<br>E 55011 Group 1 Class A<br>EN 60601-1:2006<br>EN 60601-1-2:2007 |

Buffalo Filter, LLC declares that the above mentioned products meet the provision of the Council Directive concerning Medical Devices 93/42/EEC Annex VII as amended, and is in compliance with the Essential Requirements.

**COMPANY REPRESENTATIVE:** Carrie Termin  
**TITLE:** Director of Quality Assurance and Regulatory Affairs

**SIGNATURE:**  
**DATE:** 03/13/14



BUFFALO FILTER® — A12634  
 REGISTERED



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## Declaration of Conformity SES Accessories

### PRODUCT IDENTIFICATION

| Product Groups  | Model/number  |
|---|---|
| Smoke Plume Evacuation Filters  | All ViroSafe® Filters<br>ViroVac Filters<br>Competitive Filter Replacements   |
| Smoke Evacuation Accessories  | EZLink (RSA)<br>Remote Switch Activator (RSA)<br>Foot Switches, Foot Petals<br>Mobile Carts<br>Armstand Accessory (to hold hoses and tubing)<br>LaseAdapt™ Contour TRL<br>Erbium Scanner Handpiece and Pro-Fractional Therapy Handpiece<br>Accessory Kits and Start-up Kits |
| Non-Sterile Laser, Electrosurgical, and Laparoscopic Hoses and Suction Tubing |   |
| Non-Sterile Reducer Fittings and Adapters for Hoses and Tubing                |   |
| Non-Sterile Laser Resistant Wands for Hoses and Tubing                        |   |
| Suction Canisters and Suction Canister accessories                            |   |
| Surgical Face Masks   |   |

### MANUFACTURER

| Name of company                                  | Address                                    | Representative   |
|--|--|--|
| Buffalo Filter, Division of Medtek Devices, Inc. | 5900 Genesee Street<br>Lancaster, NY 14086 | Greg Pepe, Vice President - New Product Development/ Engineering & Quality |

### AUTHORIZED REPRESENTATIVE

| Name of company | Address  | Telephone/email   |
|-----------------|--|---|
| Emergo Europe   | Molenstraat 15<br>2513 BH<br>The Hague,<br>The Netherlands | +31.70.345.8570 - phone<br>+31.70.346.7299 - fax<br>service@emergogroup.com |

**REGISTRATION INFORMATION**

| Notified Body and ID #   | CE certificate number |
|--|-----------------------|
| SGS United Kingdom, Ltd.<br>202B Worle Parkway<br>Weston-super-Mare<br>BS22 6WA UK<br>ID# 0120 | Self certified        |

**CONFORMITY ASSESSMENT**

| Device classification   | Route to compliance                                | Other Standards applied  |
|---|--|--|
| Class I, Short Term<br>Non-Invasive, Non-Active,<br>Non-Sterile Rule 1 and<br>Active, Rule 12 | Annex VII of MDD<br>93/42/EEC Council<br>Directive | QMS Medical Devices<br>EN 1041:2008<br>EN ISO 13485:2012<br>EN ISO 14971:2012<br>EN 60601-1:2006<br>EN 60601-1-2:2007<br>EN 62304:2006 |

**Buffalo Filter, LLC** declares that the above mentioned products meet the provision of the Council Directive concerning Medical Devices 93/42/EEC Annex VII as amended, and is in compliance with the Essential Requirements.

**COMPANY REPRESENTATIVE:** Carrie Termin  
**TITLE:** Director Quality Assurance and Regulatory Affairs

**SIGNATURE:**

*Carrie Termin 10/01/13*

**DATE:** 10/1/13