



GVS Filter Technology UK – Legal Manufacturer  
Medical Air Filtration Division  
NFC House  
Vickers Industrial Estate  
Mellishaw Lane  
LA3 3EN

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## E C Declaration of Conformity

We declare that the undernoted Class IIa Medical Devices are in conformity with the essential requirements and provisions of EC Directive 93/42/EEC and following changes (2007/47/EEC), Annex V Harmonised Standards.

### Device Description

Products as per attached product schedule.

### Directives:

Medical Devices Directive 93/42/EEC via the route of Annex V, products are Class IIa, UK Statutory Instrument SI 618 2002 and other applicable standards and regulatory requirements listed in Section 7 of the GVS Filter Technology – Medical Air Filtration Division technical data file.

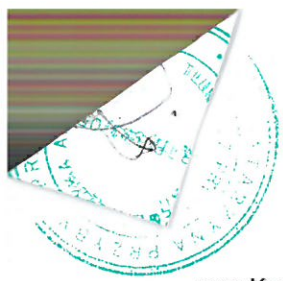
Certificate number 690080 issued by BSI Group, The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands with Notified Body Number 2797.

EU Authorised Representative: GVS S.p.A, Via Roma 50, 40069 Zola Predosa, Bologna, Italy.

This Declaration of conformity is issued under the sole responsibility of the legal manufacturer.

Signed by.....  
Massimo Scagliarini  
GVS UK Managing Director

Date: 7<sup>th</sup> March 2019



mgr Katarzyna Przybyś-Preiskorn

Tłumaczka przysięgła języka angielskiego

przy Ministerstwie Sprawiedliwości

Nr TP/883/05

05-410 Józefów, Spacerowa 43b

tel/fax (+22) 789 29 37

[tłumaczenie z jęz. angielskiego – przetłumaczono tylko stronę 1 dokumentu]

**GVS Filter Technology UK-  
Legal Manufacturer  
Medical Air Filtration Division**  
NFC House  
Vickers Industrial Estate  
Mellishaw Lane  
Wielka Brytania LA3 3 EN  
*[dane teleinformatyczne]*

Deklaracja zgodności WE

Oświadczamy, że wymienione poniżej wyroby medyczne klasy II są zgodne z zasadniczymi wymaganiami i postanowieniami dyrektywy WE 93/42 z poprawkami (2007/47/ EWG), Załącznik V Normy zharmonizowane .

**Opis wyrobu**

Wyroby wymienione w załączniku.

**Dyrektywy:**

Dyrektywa o wyrobach medycznych 93/42/EWG poprzez załącznik V; wyroby klasy IIa, brytyjski instrument ustawowy SI 618 2002, inne odnośne normy wymienione w Sekcji 7 dokumentacji technicznej GVS Filter Technology – Medical Air Filtration Division.

Numer certyfikatu 690080 nadany przez BSI Group, spółkę holenderską z siedzibą pod



adresem Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Holandia będącą jednostką notyfikowaną o numerze 2797.

Autoryzowany przedstawiciel w UE to GVS Sp.A., Via Roma 50, 40069 Zola Predosa, Bolonia, Włochy.

Niniejsza Deklaracja Zgodności została wystawiona na wyłączną odpowiedzialność prawnie zatwierdzonego producenta.

Podpisane przez *[podpis nieczytelny]*

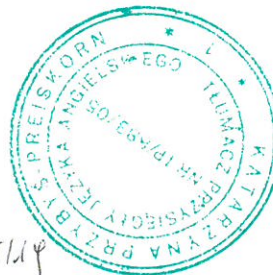
Massimo Scaglianni

Dyrektor Zarządzający GVS UK

Dnia 7 marca 2019 r.

Nr dok. TF Sec. 3

Wersja 39



**POŚWIADCZAM, ŻE POWYŻSZE TŁUMACZENIE JEST  
ZGODNE Z PRZEDSTAWIONYM MI DOKUMENTU**

**mgr KATARZYNA PRZYBYS-PREISKORN**

**TŁUMACZ PRZYSIĘGLY JĘZYKA ANGIELSKIEGO**

**JÓZEFÓW, DN. 28.03.2019 Nr REPERTORIUM 116107114**

*[Podpis]*

9080/750  
9085/751  
9500/01  
9500/02  
9500/03  
9500/04  
9500/710  
9500/750  
A620/40/61  
A620/41/61  
A620/42/61  
A620/43/61  
A620/60/61

MICRO Angled HME  
MICRO Lo-Volume HME  
Tracheal HME  
Tracheal  
Tracheal Blue HME  
Tracheal with coiled paper HME  
Micro tracheal  
Micro Tracheal  
Expandable Tubing with Elbow  
Expandable Tubing with Elbow  
Expandable Tubing with Double  
Expandable Tubing with Double  
Attachment

**Category 2 - Electrostatic filters and attachments for anaesthesia, respiratory and critical care / Pleated mechanical filters and attachments for anaesthesia, respiratory and critical care.**

1200/08  
1200/20  
1210/09  
1210/09  
1420/01  
1420/03  
1420/03BOK  
1460/00  
1460/06  
1500/01  
1500/02  
1500/03  
1600/01  
2800/01  
2800/01BFBK  
2800/01BMBK  
2800/01DAK  
2800/01DJK  
2800/01DJK  
2800/02  
2800/02BFBK  
2800/02BWBK  
2800/02DAK  
2800/03  
2800/03BFBK  
2800/03DAK  
2800/03DJK  
2800/10  
2800/10DAK  
2800/15  
2800/17  
2800/17BFBK  
2800/17DAK  
2800/21  
2800/21BFBK

Mediplex Autoclavable Filter  
Mediplex Autoclavable Filter  
Autoclavable Filter  
Medguard  
Medguard  
Medguard + Connector  
High efficiency pad system  
High efficiency pad system  
HEPA Filter  
Filter Hepa Monnal T60  
Mediprema canister filter  
Clinical Nebuliser  
Spirogard  
Spirogard with Nose Clip  
Spirogard with Mouthpiece  
Spirogard with Nose Clip and Bite Grip  
Spirogard with Bite Grip, Mouthpiece and Nose  
Spirogard with Mouthpiece and Nose Clip  
Spirogard  
Spirogard with Nose Clip  
Spirogard with Mouthpiece  
Spirogard with Nose Clip and Bite Grip  
Spirogard  
Spirogard with Nose Clip  
Spirogard with Nose Clip and Bite Grip  
Spirogard with Mouthpiece and Nose Clip  
Spirogard  
Spirogard with Nose Clip and Bite Grip  
Spirogard  
Spirogard with Nose Clip  
Spirogard with Nose Clip and Bite Grip  
Spirogard Integral Mouthpiece  
Spirogard Integral Mouthpiece with Nose Clip

**Product Schedule**

**Category 1 - HME Devices for anaesthesia, respiratory and critical care / HMEF filters for anaesthesia, respiratory and critical care.**

4244/711  
4244/712  
4331/01  
4331/01DFK  
4244/761  
4333/760  
4333/761  
4333/762  
4333/770  
4333/771  
4333/772  
9064/761  
9065/760  
4333/01  
4333/01BKN  
4333/01DBK  
4333/01DEK  
4333/01DDK  
4333/01DFK  
4333/01DGK  
4333/710  
4333/711  
4333/712  
4333/712BKN  
4333/721  
4333/750  
4333/751  
4333/752  
4333/761  
8866/100  
8866/100DEK  
8866/50  
9064/100  
9064/100BKN  
9064/711  
9064/751  
9065/710  
9065/750  
9066/50  
9066/711  
9066/751  
9067/710  
9067/750  
9080/100  
9080/100BKN  
9080/710

MAXI HME Pleat  
MAXI HME Pleat Without Port  
ECO HMEF With Connectors  
Eco HMEF With Connectors  
Eco-therm HEPA filter with coil paper HME  
Eco MAXI angled coil paper HMEF  
Eco MAXI straight coil paper HMEF  
Eco MAXI straight coil paper HMEF  
Eco MAXI angled coil paper HME  
Eco MAXI straight coil paper HME  
Eco MAXI straight coil paper HME  
Eco MAXI straight coil paper HME  
Eco MIDI straight coil paper HMEF  
Eco MIDI angled coil paper HMEF  
Eco HMEF  
Eco HMEF and elbow  
Eco HMEF + tube + connectors  
Eco HMEF + tube + connectors  
Eco HMEF + tube + connectors  
HMEF, Luer Lid with Expandable  
Eco HMEF with connectors  
MAXI Angled HMEF  
MAXI Straight HMEF  
MAXI Straight HMEF + elbow  
Eco HMEF  
Eco Range HMEF (white foam)  
MAXI Angled HME  
MAXI HME  
MAXI HME  
HMEF Adult Straight Lid Luer  
Comfort fit HMEF  
Comfort fit HMEF + tube + connectors  
Comfort fit HME  
Midi HMEF  
Midi HMEF with elbow  
MIDI HMEF  
MIDI HME  
MIDI Angled HMEF  
MIDI Angled HME  
Paediatric Slimline HME  
MINI HMEF  
MINI HME  
MINI Angled HMEF  
MINI Angled HME  
Neo-natal HMEF  
Neo Natal HMEF  
MICRO Mini Angled HMEF

4244/01DEK  
4244/02  
4244/02BLK  
4244/04  
4244/700  
4244/701  
4244/702  
4444/01 (4222/02)  
4444/01BWK (4222/02)  
4444/64  
4444/66 (4222/02)  
6421/04  
6421/04BGK  
6421/04BPK  
6888/01  
6888/20  
8444/01(4244/02)  
8444/27  
8866/01  
9066/701  
9067/700  
9070/01  
9070/01BNK  
9070/01DDK  
9071/01  
9080/01  
9080/700

Maxi Pleat with connectors  
Heat exchange, small volume  
ECO Maxi-pleat with connector  
ECO maxi-pleat  
MAXI Maxi Angled Pleat  
Eco Maxi Pleat  
MAXI Maxi Pleat  
Slimline Bacterial/Viral  
Slimline Electrostatic with mouthpiece  
Air Liquide ICARE Silencer  
Ultra High Efficiency Slimline  
Insufflation  
Hi Flow Insufflation Kit  
Insufflation kit with 3M tube  
Maxi pleat/2  
Maxi pleat  
Maxi pleat/1  
Maxi pleat  
Comfort fit bacterial/viral  
MINI Filter  
MINI Angled Filter  
Paediatric Slimline  
Paediatric slimline  
Paediatric with catheter  
Paediatric Slimline  
Neo-natal  
MICRO Angled Filter

### Category 3 - Activated Carbon and Smoke Evacuation Filters

1898/01  
1898/03  
1898/09  
2200/47  
2200/4788K  
2200/47BDK  
5250/20  
5250/25  
Scavenger Filter  
Scavenger Filter  
Goebertus Scavenger Filter  
Smoke Filter  
Smoke Set  
Smoke Set  
Epsilon Filter NO Scrubber  
Zero Filter

### Category 4 - Vent, Suction, Insufflation and Irrigation

2000/01  
2000/50  
2000/51  
2000/52  
2000/53  
2000/54  
2000/02  
2000/05  
2000/05BAK  
2000/05DLK  
2000/06  
2000/07  
Vent filter  
Suction Filter  
Suction Filter  
Suction Filter  
Suction Filter  
Suction Filter  
Vent Filter - Autoclavable  
Vent Filter  
Vent Filter Set  
Vent Filter Set  
Vent Filter  
Vent Filter - Autoclavable

2800/22  
2800/228FK  
2800/22DAK  
2800/30  
2800/728  
2800/R1  
2800/R2  
2800/R3  
2800/11  
2800/23  
2800/24  
2800/25  
2800/26  
2800/27  
3000/03  
3000/04  
3000/07  
3000/08  
3000/11  
3000/12  
3200/03  
3200/08  
3500/01  
3700/01  
3700/02  
4020/01  
4020/03  
4020/06  
4100/20  
4100/25  
4100/30  
4100/31  
4100/92  
4100/725  
4100/735  
4220/01  
4220/04  
4220/048TK  
4220/048VK  
4222/01  
4222/018WK  
4222/01DFK  
4222/02  
4222/028WK  
4222/03  
4222/700  
4222/701  
4222/702  
4222/703  
4244/01  
4244/01DBK

Spiroguard  
Spiroguard with Nose Clip  
Spiroguard with Nose Clip and Bite Grip  
Spiroguard Integral Mouthpiece  
Compact Electrostatic Spirometry Filter  
Spiroguard Re-usable  
Spiroguard Re-usable  
Spiroguard Re-usable  
Spiroguard Integral mouthpiece  
Spiroguard KOKO with Integral mouthpiece side  
Spiroguard KOKO  
Spiroguard Medisoft with Integral mouthpiece  
Spiroguard Medisoft  
Spiroguard with Integral Mouthpiece  
Multi-vent  
Multi-vent tapered  
Multi-vent  
Multi-vent  
Multi-vent flat top  
Multi-vent flat top  
Platinum Invacare  
Refill for EverFlo  
Ventilator Machine Pre-Filter  
Intake Filter  
Inogen Air Intake Filter  
ECO Machine Filter  
Single Walled Machine Filter  
ECO Machine Filter  
Main Air Intake Filter  
Oxygen Concentrator Filter  
Oxygen Concentrator Filter  
Oxygen Concentrator Filter  
Oxygen Concentrator Filter  
Oxygen Concentrator Filter  
Oxygen Concentrator Filter  
Eco maxipleat  
ECO Filter  
F&P Dryline Insufflation Set  
Insufflation kit  
ECO slimline  
Eco filter and mouthpiece  
Electret, Luer Lid + Expandable Tube  
ECO slimline  
Eco Slimline and mouthpiece  
ECO slimline  
MAXI Maxi Angled Filter  
Eco Maxi Filter  
MAXI Maxi Filter  
MAXI Maxi Filter  
ECO maxi-pleat  
Pleated filter and collapsible tube

90mm Suction Filter  
90mm Smoke Evacuation Filter

2000/08  
2000/09  
2000/12  
2000/16  
2000/17  
2000/18  
2000/18BEK  
2000/20  
2000/22  
2000/31  
2000/35  
2000/37  
2000/38  
2000/39  
2000/42  
2000/45  
2000/70  
A498  
A499  
2200/01  
2200/01BCK  
2200/01DKK  
2200/02  
2200/05  
2200/05BRK  
2200/06  
2200/11  
2200/15  
2200/16  
2200/21  
2200/25  
2200/25BUK  
2200/26  
2200/33  
2200/35  
2200/36  
2200/48  
2200/48BK  
2200/49  
2200/52  
2200/55  
2200/56  
2200/60  
2200/62  
2200/62BHK  
2200/65  
2200/66  
2200/70  
2200/71  
2200/902  
2200/910

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Vent Filter  
Vent Filter  
Vent Filter  
Vent Filter  
Vent filter  
Vent Set  
Vent Filter  
Maquet transducer filter  
Vent Filter  
Vent filter  
Vent filter  
Vent filter  
Vent Filter  
Vent Filter  
Insufflation Filter  
Small anti-bacterial filter  
Suction Irrigation Kit  
Suction Irrigation Set  
Insufflation Filter  
Insufflation Set  
Insufflation Set  
Suction Filter  
Insufflation Filter  
Insufflation Set  
Suction filter  
Suction filter  
Insufflation Filter  
Suction filter  
Insufflation Filter  
Insufflation Set  
Suction filter  
Insufflation filter  
Suction filter  
Suction filter  
Insufflation filter  
Insufflation Set  
Insufflation Filter  
Sequal suction filter  
Suction Atmos Filter  
Insufflation Filter  
Suction filter  
Insufflation filter  
Insufflation Set  
Insufflation filter  
Insufflation Filter  
Suction Filter  
Suction filter  
90MM Suction Filter  
90mm Suction Filter