



GVS Filter Technology UK – Legal Manufacturer
Medical Air Filtration Division
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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: 7th March 2019

Product Schedule

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

4244/711	MAXI HME Pleat
4244/712	MAXI HME Pleat Without Port
4331/01	ECO HMEF With Connectors
4331/01DFK	Eco Hmef With Connectors
4244/761	Eco-therm HEPA filter with coil paper HME
4333/760	Eco MAXI angled coil paper HMEF
4333/761	Eco MAXI straight coil paper HMEF
4333/762	Eco MAXI straight coil paper HMEF
4333/770	Eco MAXI angled coil paper HME
4333/771	Eco MAXI straight coil paper HME
4333/772	Eco MAXI straight coil paper HME
9064/761	Eco MIDI straight coil paper HMEF
9065/760	Eco MIDI angled coil paper HMEF
4333/01	Eco HMEF
4333/01BNK	Eco HMEF and elbow
4333/01DBK	Eco HMEF + tube + connectors
4333/01DEK	Eco HMEF + tube + connectors
4333/01DDK	Eco HMEF + tube + connectors
4333/01DFK	HMEF, Luer Lid with Expandable
4333/01DGK	Eco HMEF with connectors
4333/710	MAXI Angled HMEF
4333/711	MAXI Straight HMEF
4333/712	MAXI Straight HMEF + elbow
4333/712BNK	Eco HMEF
4333/721	Eco Range HMEF (white foam)
4333/750	MAXI Angled HME
4333/751	MAXI HME
4333/752	MAXI HME
4333/761	HMEF Adult Straight Lid Luer
8866/100	Comfort fit HMEF
8866/100DEK	Comfort fit HMEF + tube + connectors
8866/50	Comfort fit HME
9064/100	Midi HMEF
9064/100BNK	Midi HMEF with elbow
9064/711	MIDI HMEF
9064/751	MIDI HME
9065/710	MIDI Angled HMEF
9065/750	MIDI Angled HME
9066/50	Paediatric Slimline HME
9066/711	MINI HMEF
9066/751	MINI HME
9067/710	MINI Angled HMEF
9067/750	MINI Angled HME
9080/100	Neo-natal HMEF
9080/100BNK	Neo Natal HMEF
9080/710	MICRO Mini Angled HMEF

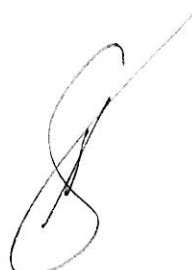
9080/750	MICRO Angled HME
9085/751	MICRO Lo-Volume HME
9500/01	Tracheal HME
9500/02	Tracheal
9500/03	Tracheal Blue HME
9500/04	Tracheal with coiled paper HME
9500/710	Micro tracheal
9500/750	Micro Tracheal
A620/40/61	Expandable Tubing with Elbow
A620/41/61	Expandable Tubing with Elbow
A620/42/61	Expandable Tubing with Double
A620/43/61	Expandable Tubing with Double
A620/60/61	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	Medipleat Autoclavable Filter
1200/20	Medipleat Autoclavable Filter
1210/09	Autoclavable Filter
1420/01	Medguard
1420/03	Medguard
1420/03BOK	Medguard + Connector
1460/00	High efficiency pad system
1460/06	High efficiency pad system
1500/01	HEPA Filter
1500/02	Filter Hepa Monnal T60
1500/03	Mediprema canister filter
1600/01	Clinical Nebuliser
2800/01	Spiroguard
2800/01BFK	Spiroguard with Nose Clip
2800/01BMK	Spiroguard with Mouthpiece
2800/01DAK	Spiroguard with Nose Clip and Bite Grip
2800/01DHK	Spiroguard with Bite Grip, Mouthpiece and Nos
2800/01DJK	Spiroguard with Mouthpiece and Nose Clip
2800/02	Spiroguard
2800/02BFK	Spiroguard with Nose Clip
2800/02BWK	Spiroguard with Mouthpiece
2800/02DAK	Spiroguard with Nose Clip and Bite Grip
2800/03	Spiroguard
2800/03BFK	Spiroguard with Nose Clip
2800/03DAK	Spiroguard with Nose Clip and Bite Grip
2800/03DJK	Spiroguard with Mouthpiece and Nose Clip
2800/10	Spiroguard
2800/10DAK	Spiroguard with Nose Clip and Bite Grip
2800/15	Spiroguard
2800/17	Spiroguard
2800/17BFK	Spiroguard with Nose Clip
2800/17DAK	Spiroguard with Nose Clip and Bite Grip
2800/21	Spiroguard Integral Mouthpiece
2800/21BFK	Spiroguard Integral Mouthpiece with Nose Clip

2800/22
2800/22BFK
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
4220/04BTK
4220/04BVK
4222/01
4222/01BWK
4222/01DFK
4222/02
4222/02BWK
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



4244/01DEK	Maxi Pleat with connectors
4244/02	Heat exchange, small volume
4244/02BLK	ECO Maxi-pleat with connector
4244/04	ECO maxi-pleat
4244/700	MAXI Maxi Angled Pleat
4244/701	Eco Maxi Pleat
4244/702	MAXI Maxi Pleat
4444/01 (4222/02)	Slimline Bacterial/Viral
4444/01BWK (4222/02)	Slimline Electrostatic with mouthpiece
4444/64	Air Liquide ICARE Silencer
4444/66 (4222/02)	Ultra High Efficiency Slimline
6421/04	Insufflation
6421/04BGK	Hi Flow Insufflation Kit
6421/04BPK	Insufflation kit with 3M tube
6888/01	Maxi pleat/2
6888/20	Maxi pleat
8444/01(4244/02)	Maxi pleat/1
8444/27	Maxi pleat
8866/01	Comfort fit bacterial/viral
9066/701	MINI Filter
9067/700	MINI Angled Filter
9070/01	Paediatric Slimline
9070/01BNK	Paediatric slimline
9070/01DDK	Paediatric with catheter
9071/01	Paediatric Slimline
9080/01	Neo-natal
9080/700	MICRO Angled Filter

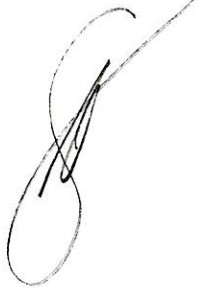
Category 3 – Activated Carbon and Smoke Evacuation Filters.

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

Category 4 - Vent. Suction, Insufflation and Irrigation

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

2000/08	Vent Filter
2000/09	Vent Filter
2000/12	Vent Filter
2000/16	Vent Filter
2000/17	Vent Filter
2000/18	Vent filter
2000/18BEK	Vent Set
2000/20	Vent Filter
2000/22	Maquet transducer filter
2000/31	Vent Filter
2000/35	Vent filter
2000/37	Vent filter
2000/38	Vent filter
2000/39	Vent Filter
2000/42	Vent Filter
2000/45	Insufflation Filter
2000/70	Small anti-bacterial filter
A498	Suction Irrigation Kit
A499	Suction Irrigation Set
2200/01	Insufflation Filter
2200/01BCK	Insufflation Set
2200/01DKK	Insufflation Set
2200/02	Suction Filter
2200/05	Insufflation Filter
2200/05BRK	Insufflation Set
2200/06	Suction filter
2200/11	Suction filter
2200/15	Insufflation Filter
2200/16	Suction filter
2200/21	Suction filter
2200/25	Insufflation Filter
2200/25BUK	Insufflation Set
2200/26	Suction filter
2200/33	Insufflation filter
2200/35	Suction filter
2200/36	Suction filter
2200/48	Insufflation filter
2200/48BIK	Insufflation Set
2200/49	Insufflation Filter
2200/52	Sequal suction filter
2200/55	Suction Atmos Filter
2200/56	Insufflation Filter
2200/60	Suction filter
2200/62	Insufflation filter
2200/62BHK	Insufflation Set
2200/65	Insufflation filter
2200/66	Insufflation Filter
2200/70	Suction Filter
2200/71	Suction filter
2200/902	90MM Suction Filter
2200/910	90mm Suction Filter



2200/911
2200/947

90mm Suction Filter
90mm Smoke Evacuation Filter

