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

Paulo Raquel
GVS UK Managing Director

Date: 10/05/21

Product Schedule

Category 1 – HME Devices for anaesthesia, respiratory and critical care/HMEF filters for anaesthesia Respiratory and critical care

4244/03	ECO MAXI Pleat
4244/711	MAXI HME Pleat
4244/712	MAXI HME Pleat Without Port
4244/761	Eco-therm HEPA filter with coil paper HME
4331/01	ECO HMEF
4331/01DFK	Eco HMEF With Connectors
4331/01DGK	Eco HMEF With Connectors
4331/50	ECO Maxi HME
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 Tube
4333/01DGK	Eco HMEF with connectors
4333/50	ECO Maxi Straight HME
4333/710	MAXI Angled HMEF
4333/711	MAXI Straight HMEF
4333/712	MAXI Straight HMEF
4333/712BNK	MAXI Straight HMEF + elbow
4333/714	ECO Maxi Angled HMEF
4333/721	Eco Range HMEF (white foam)
4333/750	MAXI Angled HME
4333/751	MAXI HME
4333/752	ECO Maxi HME
4333/754	ECO Maxi Angled HME
4333/760	Eco MAXI angled coil paper HMEF
4333/761	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
8866/50	Comfort fit HME
8866/100	Comfort fit HMEF
8866/100DEK	Comfort fit HMEF + tube + connectors
9064/711	MIDI HMEF
9064/711BNK	MIDI HMEF + elbow
9064/751	MIDI HME
9064/761	Eco MIDI straight coil paper HMEF

9065/710	MIDI Angled HMEF
9065/750	MIDI Angled HME
9065/760	Eco MIDI angled coil paper HMEF
9065/770	Eco MIDI angled coil paper HME
9066/711	MINI HMEF
9066/751	MINI HME
9066/761	Eco MINI straight coil paper HMEF
9067/710	MINI Angled HMEF
9067/750	MINI Angled HME
9067/760	Eco MINI angled coil paper HMEF
9080/100	Neo-natal HMEF
9080/100BNK	Neo Natal HMEF with elbow
9080/710	MICRO MINI angled HMEF
9080/750	MICRO angled HME
9085/751	MICRO Lo-Volume HME
9085/771	ECO Micro Lo-Volume coil paper HME
9500/01	Tracheal HME
9500/03	Tracheal Blue HME
9500/04	Tracheal HME
9500/710	Micro tracheal
9500/750	Micro Tracheal

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
2800/01	Spiroguard
2800/01BFK	Spiroguard with Nose Clip
2800/01BMK	Spiroguard with Bite Grip
2800/01DAK	Spiroguard with Nose Clip and Bite Grip
2800/01DHK	Spiroguard with Bite Grip, Mouthpiece, Nose Clip
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	
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
2800/21	Spiroguard Integral Mouthpiece
2800/21BFK	Spiroguard Integral Mouthpiece with Nose Clip
2800/22	Spiroguard
2800/22BFK	Spiroguard with Nose Clip

2800/22DAK	Spiroguard with Nose Clip and Bite Grip
2800/23	Spiroguard with Integral mouthpiece side
2800/24	Spiroguard
2800/25	Spiroguard with Integral mouthpiece
2800/26	Spiroguard
2800/27	Spiroguard with Integral Mouthpiece
2800/30	Spiroguard Integral Mouthpiece
2800/31	Spiroguard Integral Mouthpiece
2800/31BFK	Spiroguard Integral Mouthpiece with Nose Clip
2800/32	Spiroguard
2800/728	Compact Electrostatic Spirometry Filter
2800/729	Compact Electrostatic Spirometry Filter
2800/R1	Spiroguard Re-usable
2800/R2	Spiroguard Re-usable
2800/R3	Spiroguard Re-usable
3000/03	Multi-vent
3000/04	Multi-vent tapered
3000/07	Multi-vent
3000/11	Multi-vent flat top
3000/12	Multi-vent flat top
3000/740	Expiratory Filter
4020/01	ECO Machine Filter
4020/03	Single Walled Machine Filter
4020/06	ECO Machine Filter
4020/10	Machine Filter
4220/01	Eco maxipleat
4220/04	ECO Filter
4222/01	ECO slimline
4222/01BWK	Eco slimline and mouthpiece
4222/01DFK	Eco slimline, Luer Lid + Expandable Tube
4222/01DDK	Eco slimline+tube+connectors
4222/02	ECO slimline
4222/02BWK	Eco slimline and mouthpiece
4222/03	ECO slimline
4222/700	MAXI Maxi Angled Filter
4222/701	Eco Maxi Filter
4222/702	MAXI Maxi Filter
4222/703	MAXI Maxi Filter
4244/01	Eco maxi-pleat
4244/01DBK	Pleated filter and collapsible tube
4244/01DEK	Maxi Pleat with connectors
4244/02	ECO Maxi Pleat
4244/04	ECO maxi-pleat
4244/06	ECO maxi-pleat
4244/700	MAXI Maxi Angled Pleat
4244/701	Eco Maxi Pleat
4244/702	MAXI Maxi Pleat
4444/01	Slimline Bacterial/Viral
4444/01BWK	Slimline Electrostatic with mouthpiece

4444/06	Slimline Electrostatic with Integral Mouthpiece
4444/66	Ultra-High Efficiency Slimline
6888/01	Maxi pleat/2
6888/20	Maxi pleat
6888/21	Maxi Pleat ULPA Filter
8444/01	Maxi pleat/1
8444/27	Maxi pleat
8866/01	Comfort fit bacterial/viral
9066/701	MINI Filter
9066/701BNK	MINI Filter + elbow
9067/700	MINI Angled Filter
9080/01	Neo-natal/Bacterial/Viral
9080/700	MICRO Angled Filter

Category 3 – Activated Carbon and Smoke Evacuation Filters.

2200/47	Smoke Filter
2200/47BBK	Smoke Set
2200/47BDK	Smoke Set
2200/947	90mm Smoke Evacuation Filter

Category 4 – Vent, Suction, Insufflation and Irrigation

2000/01	Vent filter
2000/02	Vent Filter - Autoclavable
2000/05	Vent Filter
2000/05BAK	Vent Filter Set
2000/05DLK	Vent Filter Set
2000/05DTK	Vent Set
2000/05DUK	Vent Set
2000/05DWK	Vent Set
2000/05DXK	Vent 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	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
2000/53	Suction Filter

2200/01	Insufflation Filter
2200/01BCK	Insufflation Set
2200/01DKK	Insufflation Set
2200/02	Suction Filter
2200/02DIK	Suction Set
2200/05	Insufflation Filter
2200/05BRK	Insufflation Set
2200/06	Suction Filter
2200/15	Insufflation Filter
2200/25BUK	Insufflation Set
2200/25DSK	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
2200/55	Suction Filter
2200/56	Insufflation Filter
2200/62BHK	Insufflation Set
2200/65	Insufflation filter
2200/70	Suction Filter
2200/902	90MM Suction Filter
2200/911	90MM Suction Filter
6421/04	Insufflation Filter
6421/04BGK	Hi Flow Insufflation Kit
6421/04DVK	Insufflation Set