

Zuordnungsliste zwischen OWI- und Hersteller Artikelnummern

List of correspondence between OWI and manufacturer item numbers

Die nachfolgende Tabelle ist ein Anhang an die EG-Konformitätserklärung:
The following table is intended as an annex to the EC declaration of conformity:

“ EC Declaration of Conformity, (TF Sec 8, Rev. 37)“

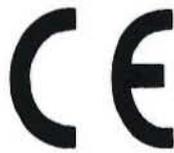
Hersteller/ *manufacturer*: GVS filter technology
Datum/ *date*: 21.05.2014

Die vorstehende EG-Konformitätserklärung gilt auch für die nachfolgend aufgeführten Artikel:
The before mentioned EC declaration of conformity is also valid for the following items:

OWI-Artikelnummer <i>(OWI item number)</i>	Artikelnummer oder -bezeichnung des Herstellers <i>(Manufacturer item number or name)</i>
A5663	2200/65 Insufflation Filter (Cat 9. Suction Filters)

Datum: 23.12.2014
erstellt von/ *issued by*: Birger Lange (RA)

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This document is issued automatically and valid without signature.



0473 E C Declaration of Conformity

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

Device Description

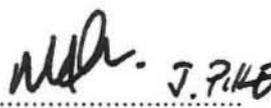
Products as per attached schedule.

Directives: Standards

Medical Devices Directive 93/42/EEC via the routes of Annex V, products are Class IIa, UK Statutory Instrument SI 618 2002, BS EN ISO 13485 and other standards listed in Section 3 of the GVS Filter Technology – Medical Air Filtration Division technical data file.

The design and production phases satisfy the prescriptions of the **ISO 9001** (certificate Intertek No: 615) and **ISO 13485** (certificate Intertek No: 615C) Quality Management Systems.

Certificate number issued by Amtac Certification Services Limited, the appointed Notified Body whose designated number is 0473

Signed by  J. PIKE
Managing Director and/or Management Representative

Date 21/05/2014

Product Schedule

Cat 1. CPAP/BIPAP replacement machine filters

200/59 Insert pad for cat no. 1460

Cat 2. HME Devices & attachments for Anaesthesia, Respiratory and Critical Care.

4333/750	MAXI Angled HME
4333/750S	MAXI Angled HME Sterile
4333/751	MAXI HME
4333/751S	MAXI HME Sterile
4333/752	MAXI HME
6200/51	Standard HME
8866/50	Comfort fit HME
8866/50S	Comfort fit HME STERILE
9040/50	Slimline HME
9064/751	MIDI HME
9064/751S	MIDI Straight HME Sterile
9065/750	MIDI Angled HME
9065/750S	MIDI Angled HME Sterile
9066/50	Paediatric Slimline HMEF
9066/751	MINI HME
9066/751S	MINI HME Sterile
9067/750	MINI Angled HME
9067/750S	MINI HME Sterile
9080/750	MICRO Angled HME
9080/750S	MICRO HME Sterile
9085/01	Neo-natal HME tube
9085/09	Neonatal tube
9085/751	MICRO Lo-Volume HME
9085/751S	MICRO Lo-Volume HME Sterile
9500/01	Tracheal HME
9500/01S	Tracheal HME sterile
9500/02	Tracheal
9500/03	Tracheal Blue HME
9500/710	Micro tracheal
9500/710S	Micro tracheal sterile
9500/750	Micro Tracheal
9500/750S	Micro Tracheal Sterile

Cat 3. HMEF filters & attachments for Anaesthesia, Respiratory and Critical Care.

4244/711	MAXI HME Pleat
4244/711S	MAXI HME Pleat Sterile
4331/01	ECO HMEF
4331/01DFK	Eco Hmef With Connectors
4333/01	Eco HMEF
4333/01S	Eco HMEF
4333/01BNK	Eco HMEF and elbow
4333/710	MAXI Angled HMEF
4333/710S	MAXI Angled HMEF
4333/711	MAXI Straight HMEF
4333/711S	MAXI Straight HMEF Sterile
4333/712	ECO HMEF
4333/712S	ECO HMEF STERILE
4333/721	Eco Range HMEF (white foam)
4333/761	HMEF Adult Straight Lid Luer
6200/300	Standard HMEF

6200/300DDK	Multi-pleat Std + Catheter
8866/100	Comfort fit HMEF
8866/100S	Comfort fit HMEF Sterile
9040/01DDK	HMEF Bacterial/Viral
9041/01	Slimline HMEF
9041/01DDK	HMEF Bacterial/Viral
9064/100	Midi HMEF
9064/100BNK	Midi HMEF
9064/711	MIDI HMEF
9064/711S	MIDI Straight HMEF Sterile
9065/710	MIDI Angled HMEF
9065/710S	MIDI Angled HMEF Sterile
9066/711	MINI HMEF
9066/711S	MINI Straight HMEF Sterile
9067/710	MINI Angled HMEF
9067/710S	MINI Angled HMEF Sterile
9080/100	Neo-natal HMEF
9080/100BNK	Neo Natal HMEF
9080/710	MICRO Mini Angled HMEF
9080/710S	MICRO Mini Angled HMEF
3100/01	Hoffreicher
3100/02	Black Hoffreicher

Cat.4. Electrostatic filters & attachments for Anaesthesia, Respiratory and Critical Care.

100/88	Refill pads of Spiroguard
1420/01	Medguard / 1420-01
1420/03	Medguard
1420/03S	Medguard Sterile
1420/03BOK	Medguard + Connector
1420/03BOK	Medguard + Connector Sterile
1460/00	High efficiency pad system
1460/04	High efficiency pad system
1460/06	High efficiency pad system
200/88	Refill pads of Spiroguard
2800/01	Spiroguard
2800/01BFK	Spiroguard
2800/01BMK	Spiroguard
2800/01DAK	Spiroguard
2800/01DHK	Spiroguard
2800/01DJK	Spiroguard
2800/02	Spiroguard
2800/02BFK	Spiroguard
2800/02BWK	Spiroguard
2800/02DAK	Spiroguard
2800/03	Spiroguard
2800/03BFK	Spiroguard
2800/03DAK	Spiroguard
2800/03DJK	Spiroguard
2800/10	Spiroguard
2800/10DAK	Spiroguard
2800/15	Spiroguard
2800/17	Spiroguard
2800/17BFK	Spiroguard
2800/17DAK	Spiroguard
2800/21	Spiroguard
2800/21BFK	Spiroguard
2800/22	Spiroguard

2800/22BFK	SPIROGUARD
2800/22DAK	Spiroguard
2800/30	Spiroguard ref Schiller
2800/R1	Spiroguard Re-usable
2800/R10	Spiroguard Re-usable
2800/R2	Spiroguard Re-usable
2800/R3	Spiroguard Re-usable
4222/01	ECO slimline
4222/01S	ECO slimline
4222/02	ECO slimline
4222/02S	ECO slimline Sterile
4222/01BWK	Eco filter and mouthpiece
4222/01DFK	Electret,Luer Lid
4222/02BWK	Eco Slimline and mouthpiece
4222/03	ECO slimline
4222/700	MAXI Maxi Angled Filter
4222/701	Eco Maxi Filter
4222/701S	Eco Maxi Filter
4222/703	MAXI Maxi Filter
4444/01	Slimline Bacterial/Viral
4444/01BWK	Slimline Electrostatic with
4444/64	Air Liquide ICARE Silencer
4444/66	Ultra High Efficiency Slimline
5200/01	NIOX Bacterial/Viral Filter
6421/04	Insufflation
6421/04S	High Flow Insufflation Filter
6421/04BGK	Hi Flow Insufflation Kit
6421/04BGK	Hi Flow Insufflation Kit
6421/04BPK	Insufflation kit with 3M tube
7000/00	Cushion Face Mask
7000/01	Cushion Face Mask
7000/02	Cushion Face Mask
7000/03	Cushion Face Mask
7000/04	Cushion Face Mask
7000/05	Cushion Face Mask
8866/01	Comfort fit bacterial/viral
9080/700	MICRO Angled Filter
9080/700S	MICRO Angled Filter Sterile
9066/701	MINI Filter
9066/701S	MINI Filter Sterile
9067/700	MINI Angled Filter
9067/700S	MINI Angled Filter Sterile
9070/01	Paediatric Slimline
9070/01S	Paediatric slimline
9070/01BNK	Paediatric slimline
9070/01DDK	Paediatric
9071/01	Paediatric Slimline
9080/01	Neo-natal
9080/01S	Neo-natal

Cat 5. . Pleated Mechanical filters & attachments for Anaesthesia, Respiratory and Critical Care.

1200/08	Autoclavable Filter
1200/20	Autoclavable Filter
1210/09	Autoclavable Filter
1500/02	Filtre Hepa Monnal T60
1600/01	Clinical Nebuliser
1800/04	Compressor filter

3000/03	Multi-vent
3000/04	Multi-vent tapered
3000/04BSK	Multivent flat top + connector
3000/07	Multi-vent
3000/08	Multi-vent
3000/10	Multi-vent
3000/11	Multi-vent flat top
3000/12	Multi-vent flat top
3000/15	002871- MULTI VENT FILTER
3200/06	L4 New Intake Filter
3200/08	Air Safety refill for EverFlo
3600/01	Weinmann
3700/01	Intake filter
3888/01	Maxi-pleat
4220/01	Eco maxi-pleat
4220/04	ECO FILTER
4220/04BTK	F&P DRYLINE INSUFFLATION SET
4220/04BVK	Insufflation kit
4244/01	ECO maxi-pleat
4244/01S	ECO maxi-pleat - sterile
4244/02	Heat exchange, small volume
4244/02S	Eco Maxi-pleat Sterile
4244/02BLK	ECO Maxi-pleat
4244/04	ECO maxi-pleat
4244/700	MAXI Maxi Angled Pleat
4244/701	Eco Maxi Pleat
4244/701S	Eco Maxi Pleat
4244/702	MAXI Maxi Pleat
4244/702S	MAXI Maxi Pleat
6888/01	Maxi-pleat/2
6888/20	maxi pleat
8222/01	Maxi-pleat/1
8444/01	Maxi-pleat/1
8444/27	Maxi-pleat
9800/01	Minipleat
9898/01	Minipleat

Cat 6. Laparoscopic Filters, Kits and Associated Accessories.

2200/01BCK	Insufflation Set
2200/25BUK	Insufflation Set DEHP Free
2200/47	ULPA/Carbon smoke filter
2200/47BBK	Smoke Set
2200/47BDK	Smoke Set
2200/47L	Suction Filter
2200/48BIK	Insufflation Kit
2200/48BIK	Insufflation Kit
A498S	Suction Irrigation Kit
A499S	Suction Irrigation Set

Cat 7. Anaesthetic Kits and Associated Accessories.

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
A521	Adult Breathing System
A523	Y Piece Breathing System

A524	Jackson Rees Paediatric
A525	Mapleson C Water's Bag
A575	Entonox Circuit

Cat 8. Vent Filters

2000/01	Vent filter
2000/02	Vent Filter - Autoclavable
2000/05	Vent Filter
2000/05S	Vent Filter Sterile
2000/06	Vent Filter
2000/06S	Vent Filter Sterile
2000/07	Vent Filter
2000/08	Vent Filter
2000/09	Vent Filter
2000/12	Vent Filter
2000/16	Vent Filter
2000/17	Vent Filter
2000/18	Vent filter
2000/20	Vent Filter
2000/200	Oxygen Filter
2000/22	Maquet transducer filter
2000/25	Vent filter
2000/30	Vent Filter
2000/31	Vent Filter
2000/34	Vent filter
2000/35	Vent filter
2000/37	Vent filter
2000/38	FIL175-0042
2000/39	Vent Filter
2000/42	Vent Filter
2000/45	Vent Filter - Stryker
2000/70	Small anti-bacterial filter
2000/701	Vent Filter
2000/706	Hepa Filter
2000/718	Vent Filter
2000/800	Smoke Evac Filter Puck
2000/18BEK	Vent Filter + Tube
2000/25BQK	Vent Filter with Tube
2000/45	Vent Filter - Stryker
2000/60	Invacare patient filter
2000/718	Vent Filter
2200/01	Insufflation Filter
2000/05BAK	Insufflation Kit
2000/05BAK	Insufflation Kit

Cat 9. Suction Filters and Irrigation

2200/05	Insufflation Filter
2200/05S	Suction filter Sterile
2200/05BRK	Suction filter with tubing
2200/06	Suction filter
2200/11	Suction filter
2200/15	Insufflation Filter
2200/16	Suction filter
2200/26	15mm Male 8mm Barbed
2200/33	Suction filter
2200/35	Suction filter
2200/36	Suction filter

2200/48	Insufflation filter
2200/48S	Insufflation filter Sterile
2200/49	Insufflation Filter
2200/52	Sequal suction filter
2200/55	SUCTION FILTER ATMOS
2200/56	Insufflation Filter
2200/60	Suction filter
2200/62	Insufflation filter
2200/62BHK	Filter insufflation kit
2200/62BHK	Filter insufflation kit
2200/65	Insufflation filter
2200/66	Soluscope Filter
2200/67	Suction filter MG Electric
2200/69	Insufflation filter
2200/70	Air Liquide – Suction Filter
2200/902	90MM Suction Filter ASMMT
2200/910	90mm Suction Filter Maquet
2200/911	90mm Suction Filter 3A
2200/947	Ulpa filter
2300/01	Laerdal LSU filter
2300/01BJK	LSU Filter Assembly
2300/01BKK	Abbott Filter Assembly
5600/01	Hydrophobic Filter
A528	Abbott Vacuum Assembly

Cat 10. Surgical Smoke Plume Filters and Scavenging Device

1898 Series	Scavenger Filter
5100 Series	Bone Cement Filter
5250 Series	NO Filter
9777 Series	L200 Smoke Evacuation Unit
9777 Series S	L200 Smoke Evacuation Unit Sterile

Cat 11. Replacement Machine Filters

1500/01	HEPA Filter
1500/02	Filtre Hepa Monnal T60
1500/03	Mediprema canister filter
3000 Series	High Efficiency Ventilator Machine Filter
3100 Series	Hoffreicher
3200 Series	Invercare
3300 Series	Lina
3400/01	Respironics Domed (Gherkin)
3500 Series	Ventilator Filter
3700 Series	Intake Filter
3800/01	Invacare compressor inlet
3900/01	Intake Filter
4020 Series	ECO Machine Filter
4021 Series S	ECO Machine Filter Sterile
4100 Series	Main Air Intake Filter
9600 Series	High Efficiency Pleated Filter
9650/01	Combination Ulpa Carbon
9650/02	Hepa filter for L200