



## Declaration of Conformity

for M01

**European Communities Council Directive 93/42/EEC as amended by 2007/47/EC  
concerning Medical Devices as transposed into European national law by the member  
states**

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

<b>General Product Name:</b>	M01
<b>Legal Manufacturer: (Name on Label)</b>	Medical Filtration Solutions Ltd, 72 Roman Way Industrial Estate, Longridge Road, Preston, LANCS, PR2 5BE, UK.
<b>Variants:</b>	As per Appendix II (This document) – Product Listing/Schedule
<b>Intended Use:</b>	Inlet filter located between atmosphere/environment and the respiratory therapy device.
<b>MD Directive Classification:</b>	Class I
<b>Notified Body:</b>	Not Applicable for Class I
<b>EU Authorised Representative:</b>	Advena Limited. Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta.
<b>Medical Device Directive Assessment Route:</b>	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

**Name** Karl Howard

**Position** Director

**Signed**

**Date** 25/01/2021

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.



## Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN ISO 10933-1:2020	Biological evaluation of Medical Devices. Part 1 Evaluation & testing.
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
EN ISO 17510-1:2009	Sleep apnoea breathing therapy. Part 1: Sleep apnoea breathing therapy equipment

## Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
M01.4.001	Exhalation Filter disc - 200g - Ø46mm - (006.001)	63172
M01.4.002	Transducer Filter disc - 100g - Ø36mm - (006.002)	63172
M01.4.003	Fine Filter - 100g - 45 x 23 with tab - (006.003)M SERIES	63172
M01.4.004	Fine Filter - 150g - 45 x 23 with tab - (006.004)M SERIES	63172
M01.4.005	Membrane Filter - 200g - Ø67mm - (006.005)	63172
M01.4.006	Membrane Filter - 300g - Ø46.5mm - [Intair ref: 6FIL017] (old code 006.006)	63172
M01.4.007	Membrane Filter - 150g - Ø29.5mm - [Intair ref: 6FIL018] (old code 006.007)	63172
M01.4.008	Resmed S8 - MGB290 - (006.008)	63172
M01.4.009	Refill for Covidien Sandman - 100g - (005.004) (TDS only - item on hold)	63172
M01.4.010	60 x 60mm with Ø4mm central hole - MD-0015_AirWeb T4/14	63172
M01.4.011	98 x 87mm - MD-0015_AirWeb T4/14	63172
M01.4.012	120 x 120mm - MD-0015_AirWeb T4/14	63172
M01.4.013	178 x 178mm - MD-0015_AirWeb T4/14	63172
M01.4.014	Devilbiss Sleepcube & IntelliPAP ranges - 100g [customer ref: DV51D-603]	63172
M01.4.015	Puritan Bennett Goodknight 418 - 100g	63172
M01.4.016	ResMed S9 - MSB160	63172
M01.4.017	Nippy Ventilator - 60x60mm - MD-0077 (AW T4/10)	63172
M01.4.018	ResMed S9 - Hypoallergenic - 100g	63172





M01.4.019	ResMed S9 - MSB160	63172
M01.4.020	ResMed S9 - Hypoallergenic - 100g	63172
M01.4.021	Refill_Weinmann Prisma_6mm_80ppi foam	63172
M01.4.022	Refill_"M series" ( PR1 )_45 x 23 with tab_150gm	63172
M01.4.023	Ø30.5mm disc_150g [Intair ref: 6FIL019]	63172
M01.4.024	Fine Filter - 150g - 45 x 23 with tab - M SERIES	63172
M01.4.025	Ø36mm disc_200g	63172
M01.4.026	Ø30.5mm disc_150g [Intair ref: 6FIL019]	63172
M01.4.027	67.5mm Square_R2 corners_150gm_ref: Weinmann Somno-Comfort, SOMNO-soft+, Somno-Vent S/ST, Somno-Smart 2, SOMNO-vent auto-S/ST, SOMNO-vent CR, and SOMNO-set	63172
M01.4.028	78mm Square, with 4mm centre hole_ MD-0015_AirWeb T4/14	63172
M01.4.029	Breas Vivo 50 - 56mm x 56mm with 1mm Corner Rads-100gm	63172
M01.4.030	Devilbiss Sleepcube & IntelliPAP ranges - Pollen- 80ppi 6mm deep [customer ref: dv51d-602]	63172
M01.4.031	Fisher Paykel Icon Synthetic with vertical line (STRIPE) denoting side (finer/denser side)- MD-0078	63172
M01.4.032	M01.4.014 & M01.4.030 Devilbiss Multipack	63172
M01.4.033	Refill_"M series" ( PR1 )_45 x 23 with tab_100gm	63172
M01.4.034	Weinmann Prisma "UltraFine" Refill 38x59.5mm 150g	63172
M01.4.035	PR1 Pre-filter / M Series Pre-filter 44 x 23mm 45 PPI Foam - 10mm deep	63172
M01.4.036	PR1 Fine Filter 43.9 x 21.8mm 0.75rads - MD-0001 (100g)	63172
M01.4.037	Krober O2 Filter_130 x 130mm_ MD-0015 (AirWeb T4/14)	63172
M01.4.038	Fisher Paykel HC221 129 x 18.3mm with cut out ends - MD-0025 (sampled on laser - on hold)	63172
M01.4.039	Fisher Paykel HC230/600 Range with vertical line denoting side_ MD-0086	63172
M01.1.040	Trend II cartridge (moulded frame, foam & electrostatic inserts)	63172
M01.4.041	Breas Vivo 50 Foam - 56x56mm - MD-0066 (5mm - 45ppi)	63172
M01.4.042	Filter lowerside Breas 401 (type 2) en Breas 4_"j-shape" MD-0001 (100g)	63172
M01.4.043	Particulate filter backside PB - 160x110mm - MD-0067 (10mm - 30ppi)	63172
M01.4.044	Covidien PB Goodnite 418 Foam - 132x21mm - 8mm deep 45 ppi	63172
M01.4.045	Covidien PB Goodnite 420 Fine - 45x20mm with 2.5mm rads MD-0001(100g)	63172
M01.4.046	Covidien PB Goodnite 420 Foam - 48x23mm - 6mm deep - 45ppi	63172
M01.4.047	Particulate filter newlife & quietlife - 132x99mm - 18mm - 20ppi	63172



M01.4.048	Breas PV201/501 - 82x82mm - MD-0001 (100g)	63172
M01.4.049	Breas Filter Vivo 30/40 reusable filter coarse inlet - 85 x 15.5mm with tunnel MD-0040 (10mm - 45ppi)	63172
M01.4.050	Breas Filter Vivo 30/40 disposable fine inlet filter - 85x15.5mm with tunnel MD-0001 (100g)	63172
M01.4.051	Breas I sleep 10/20 Fine - 66x23mm (100g) [customer ref: 004153]	63172
M01.4.052	Breas I sleep 10/20 Coarse filter - 66x23mm - MD-0066 (5mm - 45ppi)	63172
M01.4.053	Ultrafine Rempro Harmony - 91x40mm - 16mm with 10mm tab MD-0003 (200g)	63172
M01.4.054	Foam Rempro Harmony - 94x40mm - 10mm - 60ppi	63172
M01.4.055	Legendair - 70x60mm - Laminated 10mm 80ppi & 100g	63172
M01.4.056	Filter Foam for O2 Perfect (old model) - 176x97mm - MD-0068 (12-60ppi)	63172
M01.4.057	Filter Foam for O2 Perfect (new model) - 150x97mm - MD-0068 (12 -60ppi)	63172
M01.4.058	WM23540 Somnotron/Somnosmart - 148x78mm 1mm rads MD-0002 (150g)	63172
M01.4.059	WM24096 - 67x67mm MD-0002 (150g) for SOMNOsoft+, for SOMNOsoft+, SOMNOcomfort, SOMNOvent S/ST, SOMNOvent, auto-S/ST, SOMNOsmart 2, SOMNOvent CR, somnoset	63172
M01.4.060	WM24147 - 67.6 with central hole MD-0003 (200g) SOMNOcomfort, SOMNOsoft+, SOMNOsmart 2, SOMNOvent auto-S/ST, SOMNOvent S/ST, SOMNOvent CR, SOMNOset	63172
M01.4.061	WM Ventimotion Ventilator Air Inlet - 107x57mm - 10mm-60ppi	63172
M01.4.062	Somnotron 2/3/4, Somnosmart - 160x27mm - 12mm thick - RS145 foam?	63172
M01.4.063	Somnocomfort 2 - 70x30mm - MD-0065 (8mm - 80ppi)	63172
M01.4.064	Vorfilter ST307	63172
M01.4.065	Super absorber ST308	63172
M01.4.066	Ulpa Filter ST307	63172
M01.4.067	Fluid Sperrschicht ST307	63172
M01.4.068	Ø60mm disc_200g	63172
M01.4.069	Ø86mm_MD-0007 (100g)_Refill for oxygen concentrator	63172
M01.4.070	Oxigen Salud only - (customer ref S7/Spirit/VPAP/S8 AW & laminated - MD-0017 (AWTDL4B/22) and MD-0007 (100gm)	63172
M01.4.071	Ø82mm disc_ MD-0007 (100g)_Refill for oxygen concentrator	63172
M01.4.072	Filtro BMC 11 - 52 x 30mm_MD-0083	63172
M01.4.073	Exhalation Filter disc - 200g - Ø46mm	63172





M01.1.074	Dreamstation_Fine/pollen re-fill filter_overmould frame (using filter insert SA-0062)	63172
M01.4.075	Eson Diffuser refill_Mask Nasal 'diffuser'	63172
M01.4.076	Ø36mm disc_MD-0007 (100g)	63172
M01.4.077	A30/40 Ultrafine (REMSTAR??) (REF AG1063096A)_MD-0007 (100gm) Crush Cut Variant	63172
M01.4.078	Refill to suit Icon Synthetic_MD-0015 (NO STRIPE)	63172
M01.4.079	A30/40 Reusable (REF AG1063091A)_MD-0100 (10mm, 60ppi charcoal foam)	63172
M01.4.080	A30/40 Ultrafine (REF AG1063096A)_MD-0001 (100gm) Cut & Weld Variant	63172
M01.4.081	Harmony II- Synchrony II- fine filter – ref 1005945 (200gm)	63172
M01.4.082	Philips/Respironics Cough Assist Harmony II- Synchrony II- foam filter – ref 1005964 (60ppi, 9mm deep)	63172
M01.4.083	X.Pro/Duet LX/Harmo (60ppi, 10mm deep)	63172
M01.4.084	Breas 60x62mm- Ultrafine- MD-0001 [customer ref: 2210.3000]	63172
M01.4.085	Breas 60x62mm- Charcoal foam - MD-0066 [customer ref: 2210.3001]	63172
M01.4.086	PHILIPS RESPIRONICS VISION BIPAP_Filter PN 582101 ref 1040600 190mm x 77mm- 150gm	63172
M01.4.087	Refill to suit_Somno Balance fine_(ref WM 15668)_67 x 29mm 2mm rads_MD-0002 (150gm)	63172
M01.4.088	Refill to suit_Somno Comfort / series 2_foam_(ref WM 15428)_68 x 68mm_MD-0037 (80PPI 6mm)	63172
M01.4.089	Filtro Trapecio_MD-0016	63172
M01.4.090	Ø60mm disc_MD-0014_ULPA_Bacterial disc for Airflow	63172
M01.4.091	Ø60mm disc_MD-0115 & MD-0103/0114/0116_PTFE & Meltblown_Hydrophobic combination disc for Airflow	63172
M01.4.092	Donut_OD-Ø109mm, ID-Ø18.5mm_MD-0119	63172
M01.4.093	8mm, 20 ppi, 132 x 132mm - refill to suit Krober KR4	63172
M01.4.094	Refill to suit Spiri+_39 x 19mm, 6mm deep, 80ppi (MD-0037)	63172
M01.4.095	Refill to suit Spiri+_39 x 19mm, R1.0 corners (MD-0001)	63172
M01.4.096	Ø93mm disc_MD-0124 (beige foam 10mm)	63172
M01.4.097	Ø41.5mm disc_MD-0124 (beige foam 10mm)	63172
M01.4.098	Ø59.5mm disc_MD-0010 (300gm)	63172



### Version History

Version	Compiled by	Date	Description
1.0	John Keegan	13/06/2019	First issue
2.0	Karl Howard	21/12/2020	Second Issue- Authorised Representative added for post "Brexit".
3.0	John Keegan	25/01/2021	Third Issue – Product description corrections & applicable standards updated



## Declaration of Conformity

for M02

**European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states**

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

<b>General Product Name:</b>	M02
<b>Legal Manufacturer: (Name on Label)</b>	Medical Filtration Solutions Ltd, 72 Roman Way Industrial Estate, Longridge Road, Preston, LANCS, PR2 5BE, UK.
<b>Variants:</b>	As per Appendix II (This document) – Product Listing/Schedule
<b>Intended Use:</b>	Single use filter and accessories used for infection control of Spirometry equipment
<b>MD Directive Classification:</b>	Class I
<b>Notified Body:</b>	Not Applicable for Class I
<b>EU Authorised Representative:</b>	Advena Limited. Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta.
<b>Medical Device Directive Assessment Route:</b>	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

**Name** Karl Howard **Position** Director

**Signed**  **Date** 21/12/2020

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

## Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
EN ISO 26782:2009	Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time forced expired volumes in humans.

## Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
M02.1.001	Spiro-flo - spirometry filter - ("21" - 005.008)	61097
M02.4.002	Spirometry Pad - 100g - Ø87.5mm - (005.001)	61097
M02.4.004	Spirometry Pad - 200g - Ø87.5mm - (005.003)	61097
M02.4.005	Spirometry Pad - 200g - Ø59.5mm - (005.005)	61097
M02.4.006	Spirometry Pad - 200g - Ø89mm - (005.010)	61097
M02.4.007	Spirometry Pad - 200g - Ø63mm - (005.011)	61097
M02.3.008	Bite Grip - TPO - White	61097
M02.3.009	Nose Clip Called Comfort Grip Noseclip	61097
M02.4.010	Spirometry Pad - 200g - Ø87.5mm - (005.003)	61097
M02.2.011	Spiro-flo Filter(001) with Bitegrip (008) and Noseclip (009)	61097
M02.3.012	Spiro-flo adapter_Cosmed Flowmeter Turbine	61097
M02.1.013	Spiro-flo Spirometry Filter- Conical Connector	61097
M02.2.014	Spiro-flo Filter(001) and Noseclip (009)	61097
M02.2.015	Spiro-Flo Filter with Bitegrip	61097
M02.3.016	Spiro-flo adapter_Cosmed flowmeter_X9	61097
M02.4.017	Spirometry Pad - 200g - Ø89mm -	61097
M02.4.018	Spirometry Pad - 200g - Ø63mm	61097
M02.1.020	Spiro-flo - spirometry filter - White	61097
M02.2.021	Spiro-flo Filter White with Bitegrip (008) and Noseclip (009)	61097
M02.3.022	Noseclip White called Comfort foam Noseclip	61097
M02.2.023	Spiro-flo Filter(020) and Bitegrip (008) and Noseclip (022)	61097
M02.2.024	Spiro-flo Filter White and Noseclip (009)	61097



M02.2.025	Spiro-flo Filter(001) with Bitegrip (008) and Noseclip (022)	61097
M02.2.026	Spiro-flo Filter (001) with White noseclip (022)	61097
M02.3.027	Spiro-flo adapter_KOKO 45	61097
M02.3.028	Spiro-flo adapter_Jaeger F29.8-F34	61097
M02.3.029	Spiro-flo adapter_Micromedical-Vitalograph	61097
M02.3.030	Spiro-flo adapter_Morgan M22-F34	61097
M02.3.031	Adapter_Cosmed Flowmeter Turbine	61097
M02.3.032	Adapter_Cosmed flowmeter_X9	61097

### Version History

Version	Compiled by	Date	Description
1.0	John Keegan	13/06/2019	First issue
2.0	Karl Howard	21/12/2020	Second Issue- Authorised Representative added for post "Brexit".

## Declaration of Conformity

for M03

**European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states**

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

<b>General Product Name:</b>	M03
<b>Legal Manufacturer: (Name on Label)</b>	Medical Filtration Solutions Ltd, 72 Roman Way Industrial Estate, Longridge Road, Preston, LANCS, PR2 5BE, UK.
<b>Variants:</b>	As per Appendix II (This document) – Product Listing/Schedule
<b>Intended Use:</b>	A filter to protect suction / aspirator medical device/ circuit from fluids and secretions from a patient.
<b>MD Directive Classification:</b>	Class I
<b>Notified Body:</b>	Not Applicable for Class I
<b>EU Authorised Representative:</b>	Advena Limited. Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta.
<b>Medical Device Directive Assessment Route:</b>	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

**Name** Karl Howard **Position** Director

**Signed**  **Date** 21/12/2020

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EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
ISO 10079-1:2015	Medical suction equipment. Part 1: Electrically powered suction

## Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
M03.1.003	65mm suction housing, 8mm barb connections	37798
M03.1.004	65mm suction housing, 11-15mm barb connections	37798
M03.1.009	90mm suction housing, 11-15mm barb connections	37798
M03.1.018	65mm suction housing, 11-15mm barb one side and 15mm other side.	37798

## Version History

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2.0	Karl Howard	21/12/2020	Second Issue- Authorised Representative added for post "Brexit".