# Declaration of Conformity

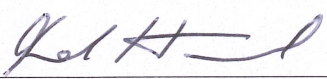
for M01

**Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices**

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

| | |
|---|---|
| **General Product Name:** | M01 |
| **Legal Manufacturer: (Name on Label)** | Medical Filtration Solutions Ltd, 72 Roman Way Industrial Estate, Longridge Road, Preston, LANCS, PR2 5BE, UK. |
| **Manufacturer's SRN:** | Not Yet Available |
| **Basic UDI-DI:** | 506055490M01CC |
| **Variants:** | As per Appendix II (This document) – Product Listing/Schedule |
| **Intended Purpose** | CPAP/BPAP unit ambient air filter, reusable. |
| **MD Regulation Classification:** | Class I |
| **Notified Body:** | Not Applicable for Class I |
| **EC Certificate:** | Not Applicable for Class I |
| **EU Authorised Representative:** | Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.<br>Tel: + 356 2546 6689.<br>Email: info@advenamedical.com |
| **EU Authorised Representative SRN:** | MT-AR-000000234 |
| **Medical Device Regulation Assessment Route:** | Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745. |

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

**Signed**  **On the date** 2021-07-20

**In Preston, Lancashire, United Kingdom for and on behalf of Medical Filtration Solutions Ltd.**

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 |
|---|---|
| Regulation (EU) 2017/745 | REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC |
| EN ISO 10933-1:2020 | Biological evaluation of Medical Devices. Part 1 Evaluation & testing. |
| 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 |
| EN ISO 20417:2021 | Medical Devices- Information to be supplied by the manufacturer. |

## Appendix II – Product Listing/Schedule

| Part/Catalogue Number | Description/Name | GMDN Code |
|---|---|---|
| M01.4.008 | Refill for Resmed S8 – Coarse | 63172 |
| M01.4.009 | Refill for Covidien Sandman – Fine | 63172 |
| M01.4.014 | Refill for Devilbiss Sleepcube & IntelliPAP ranges – Fine | 63172 |
| M01.4.015 | Refill for Puritan Bennett Goodknight 418 – Fine | 63172 |
| M01.4.016 | Refill for ResMed S9 – Coarse | 63172 |
| M01.4.017 | Refill for Nippy Ventilator inlet – Coarse | 63172 |
| M01.4.018 | Refill for ResMed S9 – Hypoallergenic – Fine | 63172 |
| M01.4.021 | Refill for Weinmann Prisma_Foam | 63172 |
| M01.4.027 | Refill for Weinmann Somno-Comfort, Soft, Vent Series- Fine | 63172 |
| M01.4.029 | Refill for Breas Vivo 50 – Fine | 63172 |
| M01.4.030 | Refill for Devilbiss Sleepcube & IntelliPAP ranges – Foam | 63172 |
| M01.4.031 | Refill for Fisher Paykel Icon – Coarse | 63172 |
| M01.4.032 | Refills for Devilbiss – M01.4.014 & M01.4.030 Multipack | 63172 |
| M01.4.033 | Refill for "M series" (PR1) with Tab- Fine | 63172 |
| M01.4.034 | Refill for Weinmann Prisma "Ultra-Fine" | 63172 |
| M01.4.035 | Refill for PR1 / M Series Pre-filter – Foam | 63172 |
| M01.4.036 | Refill for PR1 – Fine | 63172 |
| M01.4.037 | Refill for Krober O2 Filter- Coarse | 63172 |

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|---|---|---|
| M01.4.038 | Refill for Fisher Paykel HC221 | 63172 |
| M01.4.039 | Refill for Fisher Paykel HC230/600 | 63172 |
| M01.1.040 | Refill for Cartridge filter for Trend II | 63172 |
| M01.4.041 | Refill for Breas Vivo 50 – Foam | 63172 |
| M01.4.044 | Refill for Covidien PB Goodnite 418 – Foam | 63172 |
| M01.4.045 | Refill for Covidien PB Goodnite 420 – Fine | 63172 |
| M01.4.046 | Refill for Covidien PB Goodnite 420- Foam | 63172 |
| M01.4.047 | Refill for Particulate filter newlife & quietlife – Foam | 63172 |
| M01.4.048 | Refill for Breas PV201/501 – Fine | 63172 |
| M01.4.049 | Refill for Breas Filter Vivo 30/40 reusable filter – Coarse | 63172 |
| M01.4.050 | Refill for Breas Filter Vivo 30/40 – Fine | 63172 |
| M01.4.051 | Refill for Breas I sleep 10/20 Fine – Fine | 63172 |
| M01.4.052 | Refill for Breas I sleep 10/20 – Foam | 63172 |
| M01.4.055 | Refill for Legendair – Composite Fine/Foam | 63172 |
| M01.4.056 | Refill for Filter Foam for O2 Perfect (V1) – Foam | 63172 |
| M01.4.057 | Refill for Filter Foam for O2 Perfect (V2) – Foam | 63172 |
| M01.4.060 | Refill for WM24147 – SOMNOcomfort, SOMNOsoft+, SOMNOsmart 2, SOMNOvent auto-S/ST, SOMNOvent S/ST, SOMNOvent CR, SOMNOset- Fine | 63172 |
| M01.4.061 | Refill for WM Ventimotion Ventilator Air Inlet – Foam | 63172 |
| M01.4.062 | Refill for Somnotron 2/3/4, Somnosmart – Foam | 63172 |
| M01.4.063 | Refill for Somnocomfort 2 – Foam | 63172 |
| M01.4.069 | Refill for Ø86mm oxygen concentrator inlet – Fine | 63172 |
| M01.4.070 | Refill for Oxigen Salud only – (Customer ref S7/Spirit/VPAP/S8 AW – Laminated Fine/Foam) | 63172 |
| M01.1.074 | Refill for Dreamstation_Fine | 63172 |
| M01.4.075 | Refill for Eson Diffuser refill_Mask Nasal 'diffuser' | 63172 |
| M01.4.077 | Refill for A30/40 Ultrafine (REF AG1063096A)- Fine | 63172 |
| M01.4.078 | Refill to suit Icon Synthetic_Coarse | 63172 |
| M01.4.079 | Refill for A30/40 Reusable (REF AG1063091A)- Foam | 63172 |
| M01.4.080 | Refill for A30/40 Ultrafine (REF AG1063096A)- Fine | 63172 |
| M01.4.081 | Refill for Harmony II- Syncrony II- Fine | 63172 |
| M01.4.082 | Refill for Philps/Respironics Cough Assist Harmony II- Syncrony II- Foam | 63172 |
| M01.4.083 | Refill for X.Pro/Duet LX/Harmo – Foam | 63172 |
| M01.4.084 | Refill for Breas (customer ref: 2210.3000) Fine | 63172 |
| M01.4.085 | Refill for Breas 60x62mm- Charcoal foam – MD-0066 [customer ref: 2210.3001] | 63172 |
| M01.4.086 | Refill for PHILIPS RESPIRONICS VISION BIPAP_Filter PN 582101 ref 1040600- Fine | 63172 |
| M01.4.087 | Refill for Somno Balance fine_(ref WM 15668)- Fine | 63172 |
| M01.4.088 | Refill to suit_Somno Comfort / series 2_foam_(ref WM 15428) – Foam | 63172 |
| M01.4.093 | Refill for Krober KR4- Foam | 63172 |

## Version History

| Version | Compiled by | Date | Description |
|---|---|---|---|
| 1.0 | John Keegan | 2019-06-13 | First issue |
| 2.0 | Karl Howard | 2020-12-21 | Second Issue- Authorised Representative added for post "Brexit". |
| 3.0 | John Keegan | 2021-01-25 | Third Issue – Product description corrections & applicable standards updated |
| 4.0 | Karl Howard | 2021-13-07 | Fourth issue- Changes for transition to Regulation (EU) 2017/745 |
| 5.0 | Karl Howard | 2021-07-20 | Updated to address errors and assessment route |

# Declaration of Conformity

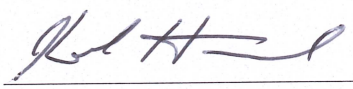
for M02

## Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

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

| | |
|---|---|
| **General Product Name:** | M02 |
| **Legal Manufacturer: (Name on Label)** | Medical Filtration Solutions Ltd, 72 Roman Way Industrial Estate, Longridge Road, Preston, LANCS, PR2 5BE, UK. |
| **Manufacturer's SRN:** | Not Yet Available |
| **Basic UDI-DI:** | 506055490M03CE |
| **Variants:** | As per Appendix II (This document) – Product Listing/Schedule |
| **Intended Purpose** | Singe use filter and accessories used for infection control of Spirometry equipment. |
| **MD Regulation Classification:** | Class I |
| **Notified Body:** | Not Applicable for Class I |
| **EC Certificate:** | Not Applicable for Class I |
| **EU Authorised Representative:** | Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.<br>Tel: + 356 2546 6689.<br>Email: info@advenamedical.com |
| **EU Authorised Representative SRN:** | MT-AR-000000234 |
| **Medical Device Regulation Assessment Route:** | Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745. |

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

**Signed**  **On the date** 2021-07-20

**In Preston, Lancashire, United Kingdom for and on behalf of Medical Filtration Solutions Ltd.**

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 |
|---|---|
| Regulation (EU) 2017/745 | REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC |
| 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 26782:2009 | Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time forced expired volumes in humans. |
| EN ISO 20417:2021 | Medica devices- Information to be supplied by the manufacturer. |

## Appendix II – Product Listing/Schedule

| Part/Catalogue Number | Description/Name | GMDN Code |
|---|---|---|
| M02.1.001 | Spiro-flo - spirometry filter | 61097 |
| M02.4.002 | Spirometry Pad - 100g - Ø87.5mm | 61097 |
| M02.4.004 | Spirometry Pad - 200g - Ø87.5mm | 61097 |
| M02.4.005 | Spirometry Pad - 200g - Ø59.5mm | 61097 |
| M02.4.006 | Spirometry Pad - 200g - Ø89mm | 61097 |
| M02.4.007 | Spirometry Pad - 200g - Ø63mm | 61097 |
| M02.3.008 | Bite Grip - TPO - White | 61097 |
| M02.3.009 | Comfort Grip Blue Noseclip | 61097 |
| M02.4.010 | Spirometry Pad - 200g - Ø87.5mm | 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 Spiromtery 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 | White 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 | 2019-06-13 | First issue |
| 2.0 | Karl Howard | 2020-12-21 | Second Issue- Authorised Representative added for post "Brexit". |
| 3.0 | Karl Howard | 2021-07-13 | Third issue- Changes for transition to Regulation (EU) 2017/745. |
| 4.0 | Karl Howard | 2021-07-20 | Updated to address errors and assessment route |

# Declaration of Conformity

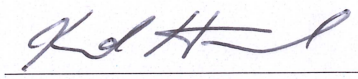
for M03

## Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

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

| | |
|---|---|
| **General Product Name:** | M03 |
| **Legal Manufacturer: (Name on Label)** | Medical Filtration Solutions Ltd, 72 Roman Way Industrial Estate, Longridge Road, Preston, LANCS, PR2 5BE, UK. |
| **Manufacturer's SRN:** | Not Yet Available |
| **Basic UDI-DI:** | 506055490M03CG |
| **Variants:** | As per Appendix II (This document) – Product Listing/Schedule |
| **Intended Purpose** | A filter to protect suction / aspirator medical device/ circuit from fluids and secretions from a patient. |
| **MD Regulation Classification:** | Class I |
| **Notified Body:** | Not Applicable for Class I |
| **EC Certificate:** | Not Applicable for Class I |
| **EU Authorised Representative:** | Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.<br>Tel: + 356 2546 6689.<br>Email: info@advenamedical.com |
| **EU Authorised Representative SRN:** | MT-AR-000000234 |
| **Medical Device Regulation Assessment Route:** | Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745. |

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

**Signed**  **On the date** 2021-07-20

**In Preston, Lancashire, United Kingdom for and on behalf of Medical Filtration Solutions Ltd.**

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 |
|---|---|
| Regulation (EU) 2017/745 | REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC |
| 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 |
| ISO 10079-1:2015 | Medical suction equipment.<br>Part 1: Electrically powered suction |
| EN ISO 20417:2021 | Medical Devices- Information to be supplied by the manufacturer. |

## 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

| Version | Compiled by | Date | Description |
|---|---|---|---|
| 1.0 | John Keegan | 2019-06-13 | First issue |
| 2.0 | Karl Howard | 2020-12-21 | Second Issue- Authorised Representative added for post "Brexit". |
| 3.0 | Karl Howard | 2021-07-13 | Third issue- Changes for transition to Regulation (EU) 2017/745 |
| 4.0 | Karl Howard | 2021-07-20 | Updated to address errors and assessment route |