# Certificate of Registration

**In accordance with 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.**

**We hereby declare that:**

- **An examination has been made of this organisation's Declaration of Conformity(s) and where appropriate Notified Body certification(s) exist.**
- **The EU Authorised Representative contract has been fulfilled.**
- **Device registrations for the medical devices mentioned within this certificate have duly been completed with an EU Competent Authority.**

**Therefore, these devices have met the requirements of the council directive and the CE mark may be applied to the products listed below.**

| Certificate No: CE/GBR/2019/03/09 | Issue Date: 21st December 2020 | Expiry Date: *31st October 2021 |
|---|---|---|

***Please note, due to the implementation date of the new medical device regulation (EU 2017/745) this certificate is subject to a review of the client's technical documentation before the 26th May 2021, whereupon a new Certificate of Registration is issued once compliance to the medical device regulation has been achieved.***

| Legal Manufacturer | EU Authorised Representative (EC REP) |
|---|---|
| **M G Electric (Colchester) Ltd**<br>Unit 5 Altbarn Close, Wyncolls Road, Colchester, Essex, CO4 9HY United Kingdom | Advena Limited, Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013 Malta. |

| Product Details, Names or Trade Names | Device Registration Reference(s) |
|---|---|
| SAM Suction Filters | DVC-MT-20-12-000650 |
| SAM 2 Collection Containers | DVC-MT-20-12-000651 |

| Competent Authority |
|---|
| **Malta Medicines Authority (MMA)**<br>Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000 Malta.<br>Tel: +356 2343 9000 Email: info.medicinesauthority@gov.mt |

| This certificate is issued by: | Authorised Signature: |
|---|---|
| **Advena Limited**<br>**Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013.**<br>**Malta. Tel: +44 1926 800153 Email: info@advenamedical.com**<br>**Registered in Malta No. C 76865** | *A. Kirby*<br>**Anthony Kirby - Managing Director (Malta)** |

# Declaration of Conformity

for **SAM Suction Filters**

**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.

| | |
|---|---|
| **General Product Name:** | SAM Suction Filters |
| **Legal Manufacturer: (Name on Label)** | M. G. Electric (Colchester) Ltd, Unit 5 Altbarn Close, Wyncolls Road, Colchester, Essex, CO4 9HY, United Kingdom |
| **Variants:** | As per Appendix II (This document) – Product Listing/Schedule |
| **Intended Use:** | In-line Filter for use with Suction Devices |
| **MD Directive Classification:** | Class I |
| **Notified Body:** | Not Applicable for Class I |
| **EU Authorised Representative:** | Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta. |
| **Medical Device Directive Assessment Route:** | 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** G. M. Martin **Position** Managing Director

**Signed** G.M.Mart **Date** 30/10/2020

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 10079-1:2015 | Medical Suction Equipment Part 1 Electrically powered suction equipment |

## Appendix II – Product Listing/Schedule

| Part/Catalogue Number | Description/Name | GMDN Code |
|---|---|---|
| MSP1002 (01-0199) | SAM Bacterial In-line Filter | 37798 |
| MSP1003 (01-0200) | SAM Hydrophobic & Bacterial In-line Filter | 37798 |
| | | |
| | | |
| | | |
| | | |

## Version History

| Version | Compiled by | Date | Description |
|---|---|---|---|
| 1.0 | G. M. Martin | 30/10/2020 | First issue including EU Representative Advena |
| | | | |

# Declaration of Conformity

for **SAM 2 Collection Containers**

**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.

| | |
|---|---|
| **General Product Name:** | SAM 2 Collection Containers |
| **Legal Manufacturer: (Name on Label)** | M. G. Electric (Colchester) Ltd, Unit 5 Altbarn Close, Wyncolls Road, Colchester, Essex, CO4 9HY, United Kingdom |
| **Variants:** | As per Appendix II (This document) – Product Listing/Schedule |
| **Intended Use:** | Collection Bottle for use with Suction unit for the aspiration of body fluids and fluids in general |
| **MD Directive Classification:** | Class I Measuring |
| **Notified Body:** | BSI Group The Netherlands B.V. (Notified Body No. 2797) |
| **CE Certificate Reference:** | CE 01938 |
| **EU Authorised Representative:** | Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta. |
| **Medical Device Directive Assessment Route:** | EC Declaration of Conformity in accordance with Annex VII of the Medical Device Directive coupled with Production Quality Assurance outlined in Annex V. |

**Name** G. M. Martin **Position** Managing Director

**Signed** G.M.Mat **Date** 30/10/2020

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

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| 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 10079-1:2015 | Medical Suction Equipment Part 1 Electrically powered suction equipment |

## Appendix II – Product Listing/Schedule

| Part/Catalogue Number | Description/Name | GMDN Code |
|---|---|---|
| SAM 2 | 2 Litre Collection Container for Suction Unit | 38476 |
| SAM 2 IU | 2 Litre Collection Container for Suction Unit for IU Procedures | 38476 |

## Version History

| Version | Compiled by | Date | Description |
|---|---|---|---|
| 1.0 | G. M. Martin | 30/10/2020 | First issue including EU Representative Advena |
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