# Declaration of Conformity

for **SAM Electric Powered Suction Units**

**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 Electric Powered Suction Units |
| **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:** | Suction unit for the aspiration of body fluids and fluids in general |
| **MD Directive Classification:** | Class IIa |
| **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.Martin **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 |
| EN 60601-1:2006 | Medical Electrical Equipment Part 1 General requirements for basic safety and essential performance |
| EN 60601-1-2:2015 | Medical Electrical Equipment Part 1-2 General requirements for basic safety and essential performance – Collateral Standard Electromagnetic disturbances – Requirements & tests |

## Appendix II – Product Listing/Schedule

| Part/Catalogue Number | Description/Name | GMDN Code |
|---|---|---|
| SAM MS | Single Bottle High Vacuum & Flow Suction Unit for ENT Micro Suction | 36777 |
| SAM 12 | Single Bottle High Vacuum & Flow Suction Unit | 36777 |
| SAM 14 | Double Bottle High Vacuum & Flow Suction Unit | 36777 |
| SAM 15 | Single Bottle High Vacuum & Flow Suction Unit for IU Procedures | 36777 |
| SAM 16 | Double Bottle High Vacuum & Flow Suction Unit for IU Procedures | 36777 |
| SAM 17 | Single Bottle Suction Unit for Thoracic Drainage | 36777 |
| SAM 18 | Single Bottle Low Vacuum & Flow Suction Unit | 36777 |
| SAM 19 | Double Bottle Low Vacuum & Flow Suction Unit | 36777 |
| SAM 35 | Double Bottle High Vacuum & Flow Suction Unit | 36777 |
| SAM 36 | Double Bottle High Vacuum & Flow Suction Unit for IU Procedures | 36777 |
| SAM420 | Single Bottle High Vacuum & Flow Suction Unit | 36777 |

## 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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