# Declaration of Conformity

for **SAM Vacuum Powered Suction Regulators**

**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 Vacuum Powered Suction Regulators |
| **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 regulator 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.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 10079-3:2014 | Medical Suction Equipment Part 3 Suction equipment powered from a vacuum or positive pressure gas source |

## Appendix II – Product Listing/Schedule

| Part/Catalogue Number | Description/Name | GMDN Code |
|---|---|---|
| SAM 50 | High Vacuum & Flow Remote Probe Suction Regulator | 36778 |
| SAM 51 | High Vacuum & Flow Direct Probe Suction Regulator | 36778 |
| SAM 52 | Low Vacuum & Flow Remote Probe Suction Regulator | 36778 |
| SAM 53 | Low Vacuum & Flow Direct Probe Suction Regulator | 36778 |
| SAM 54 | Double Bottle High Vacuum & Flow Suction Regulator Trolley | 36778 |

## Version History

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

# Declaration of Conformity Addendum

## for **SAM Vacuum Powered Suction Regulators**

This Addendum has been issued in accordance with (EU) 2017/745 Article 120 / and MDCG 2020-3. This confirms the below mentioned changes are considered to be 'non-significant' and no significant changes have been made to the device since 26th May 2021. The changes are not stipulated as significant in accordance with the MDR.

**Applicable Standards – Updates and Additions**

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

| Standard/Document Name | Description |
|---|---|
| EN ISO 13485:2016+A11:2021 | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes |
| EN ISO 20417:2021 | Medical Devices – Information to be supplied by the manufacturer |
| EN ISO 15223-1:2021 | Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied |
| EN ISO 10079-3:2022 | Medical Suction Equipment Part 3 – Suction equipment powered from a vacuum or positive pressure gas source |
| EN ISO 10079-4:2021 | Medical Suction Equipment Part 4 – General requirements |

**Applicable Standards- Removals and replacements**

The following European standards and Common Specifications have been removed or superseded in this declaration of conformity:

| Standard/Document Name | Description |
|---|---|
| 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 15223-1:2016 | Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied |
| EN ISO 10079-3:2014 | Medical Suction Equipment Part 3 Suction equipment powered from a vacuum or positive pressure gas source |

**Addition to Table 1 on 1st Page**

| | |
|---|---|
| **Basic UDI-DI:** | 506049784AA0363 SAM Vacuum Powered Suction Regulators |

**Revised Appendix II – Product Listing/Schedule**

| Part/Catalogue Number | Description/Name | GMDN / EMDN Code |
|---|---|---|
| SAM 50 | High Vacuum & Flow Remote Probe Suction Regulator | 36778 / A0601010299 |
| SAM 51 | High Vacuum & Flow Direct Probe Suction Regulator | 36778 / A0601010299 |
| SAM 52 | Low Vacuum & Flow Remote Probe Suction Regulator | 36778 / A0601010299 |
| SAM 53 | Low Vacuum & Flow Direct Probe Suction Regulator | 36778 / A0601010299 |
| SAM 54 | Double Bottle High Vacuum & Flow Suction Regulator Trolley | 36778 / A0601010299 |

**Appendix II – Product Listing/Schedule**

| Catalogue Number/UDI-DI | Description/Name | GMDN/EMDN Code |
|---|---|---|
| SAM50/ 5060497843240 | Medical pipeline vacuum regulator suction unit with remote BS probe | 36778 / A0601010299 |
| SAM50 SERRES/ 5060497843257 | Medical pipeline vacuum regulator suction unit with remote BS probe 4m, SERRES | 36778 / A0601010299 |
| SAM50.2/ 5060497843264 | Medical pipeline vacuum regulator suction unit with remote probe,1x2L reusable SAM2 plastic collection jars | 36778 / A0601010299 |
| SAM50.2 ABBOTT/ 5060497843271 | Medical pipeline vacuum regulator suction unit with remote probe,1x2L ABBOTT disposable liner system | 36778 / A0601010299 |
| SAM50.2 VACSAX/ 5060497843288 | Medical pipeline vacuum regulator suction unit with remote probe,1x2L VACSAX disposable liner system | 36778 / A0601010299 |
| SAM50.2 SERRES/ 5060497843295 | Medical pipeline vacuum regulator suction unit with remote probe,1x2L SERRES disposable liner system | 36778 / A0601010299 |
| SAM51/ 5060497843554 | Medical pipeline vacuum regulator suction unit with direct BS probe | 36778 / A0601010299 |
| SAM51.2/ 5060497843561 | Medical pipeline vacuum regulator suction unit with direct probe,1x2L reusable SAM2 plastic collection jars | 36778 / A0601010299 |
| SAM51.2 ABBOTT/ 5060497843578 | Medical pipeline vacuum regulator suction unit with direct probe,1x2L ABBOTT disposable liner system | 36778 / A0601010299 |
| SAM51.2 VACSAX/ 5060497843585 | Medical pipeline vacuum regulator suction unit with direct probe,1x2L VACSAX disposable liner system | 36778 / A0601010299 |

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|---|---|---|
| SAM51.2 SERRES/ 5060497843592 | Medical pipeline vacuum regulator suction unit with direct probe,1x2L SERRES disposable liner system | 36778 / A0601010299 |
| SAM52/ 5060497843806 | Medical pipeline vacuum regulator suction unit with remote BS probe | 36778 / A0601010299 |
| SAM52.2/ 5060497843813 | Medical pipeline vacuum regulator suction unit with remote probe,1x2L reusable SAM2 plastic collection jars | 36778 / A0601010299 |
| SAM52.2 ABBOTT/ 5060497843820 | Medical pipeline vacuum regulator suction unit with remote probe,1x2L ABBOTT disposable liner system | 36778 / A0601010299 |
| SAM52.2 VACSAX/ 5060497843837 | Medical pipeline vacuum regulator suction unit with remote probe,1x2L VACSAX disposable liner system | 36778 / A0601010299 |
| SAM52.2 SERRES/ 5060497843844 | Medical pipeline vacuum regulator suction unit with remote probe,1x2L SERRES disposable liner system | 36778 / A0601010299 |
| SAM53/ 5060497844056 | Medical pipeline vacuum regulator suction unit with direct BS probe | 36778 / A0601010299 |
| SAM53.2/ 5060497844063 | Medical pipeline vacuum regulator suction unit with direct probe,1x2L reusable SAM2 plastic collection jars | 36778 / A0601010299 |
| SAM53.2 ABBOTT/ 5060497844070 | Medical pipeline vacuum regulator suction unit with direct probe,1x2L ABBOTT disposable liner system | 36778 / A0601010299 |
| SAM53.2 VACSAX/ 5060497844087 | Medical pipeline vacuum regulator suction unit with direct probe,1x2L VACSAX disposable liner system | 36778 / A0601010299 |
| SAM53.2 SERRES/ 5060497844094 | Medical pipeline vacuum regulator suction unit with direct probe,1x2L SERRES disposable liner system | 36778 / A0601010299 |
| SAM54/ 5060497844308 | Medical pipeline vacuum regulator trolley suction unit with remote probe, 2x2L reusable SAM2 plastic collection jars | 36778 / A0601010299 |
| SAM54 ABBOTT/ 5060497844315 | Medical pipeline vacuum regulator trolley suction unit with remote probe, 2x2L ABBOTT disposable liner system | 36778 / A0601010299 |
| SAM54 VACSAX/ 5060497844322 | Medical pipeline vacuum regulator trolley suction unit with remote probe, 2x2L VACSAX disposable liner system | 36778 / A0601010299 |
| SAM54 SERRES/ 5060497844339 | Medical pipeline vacuum regulator trolley suction unit with remote probe, 2x2L SERRES disposable liner system | 36778 / A0601010299 |
| SAM54 ABBOTT 6/ 5060497844346 | Medical pipeline vacuum regulator trolley suction unit with remote probe, 6x2L ABBOTT disposable liner system | 36778 / A0601010299 |
| SAM54 SERRES 6/ 5060497844353 | Medical pipeline vacuum regulator trolley suction unit with remote probe, 6x2L SERRES disposable liner system | 36778 / A0601010299 |

## Change Table

| Date of Change | Description of Change | Signature |
|---|---|---|
| 08/05/2024 | • Adding Basic UDI-DI (506049784AA0363) SAM Vacuum Powered Suction Regulators as an Addition to Table 1 on 1st Page.<br>• Adding GMDN/ EMDN Code (36778 / A0601010299) in Appendix II- Product Listing Schedule | |
| 22/10/2025 | The following standards have been removed from the applicable standards list:<br>• EN 1041:2008 – Information supplied by the manufacturer of medical devices<br>• EN ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes<br>• EN ISO 15223-1:2016 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied<br>• EN ISO 10079-3:2014– Medical Suction Equipment Part 3 Suction equipment powered from a vacuum or positive pressure gas source<br>The following updated and additional standards have been added to the applicable standards list:<br>• EN ISO 13485:2016+A11:2021 – Medical devices – Quality management systems – Requirements for regulatory purposes.<br>• EN ISO 10079-3:2022 – Medical suction equipment – Part 3: Suction equipment powered from a vacuum or positive pressure gas source.<br>• EN ISO 10079-4:2021 – Medical suction equipment – Part 4: General requirements<br>• EN ISO 20417:2021 – Medical devices – Information to be supplied by the manufacturer<br>• EN ISO 15223-1:2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied | |
| 20/10/2026 | Updated Appendix II – Product Listing/Schedule to expand the previous single general product entry into individual listings for **27 SAM Vacuum Powered Suction Regulators** Unit variants, specifying each product's **Catalogue Number/UDI-DI, product description, and GMDN/EMDN Code.** | |

## Version History

| Version | Compiled by | Date | Description |
|---|---|---|---|
| 2.0 | G. M. Martin | 08/05/2024 | Added Basic UDI-DI, updated applicable standards, added EMDN Code. |
| 3.0 | G. M. Martin | 22/10/2025 | Adding an addendum document for applicable standards and changes in line with MDD-to-MDR transition, without revising the original DOC (Version 1.0) |
| 4.0 | G. M. Martin | 20/10/2026 | Addendum to DOC – Updated Appendix II Product Listing/Schedule to include Catalogue Number/UDI-DI, Description/Name and GMDN/EMDN Code. |