# 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.

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| **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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# Declaration of Conformity Addendum

## for **SAM Electric Powered Suction Units**

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 10079-4:2021 | Medical Suction Equipment Part 4 – General requirements |
| EN 60601-1:2006+A1:2013 | Medical Electrical Equipment Part 1 General requirements for basic safety and essential performance |
| EN ISO 20417:2021 | Medical Devices – Information to be supplied by the manufacturer |

**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 60601-1:2006 | Medical Electrical Equipment Part 1 General requirements for basic safety and essential performance |

**Appendix II – Product Listing/Schedule**

| Catalogue Number/UDI-DI | Description/Name | GMDN/EMDN Code |
|---|---|---|
| SAM 12/01010101/ 5060497840003 | Medical electric suction unit static with UK plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 12/01010102/ 5060497840010 | Medical electric suction unit mobile with UK Plug, 1x2L reusable SAM2 plastic collection container jar | 63648/A0601010201 |
| SAM 12/01010501/ 5060497840027 | Medical electric suction unit static with EU plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 12/01010502/ 5060497840034 | Medical electric suction unit mobile with EU plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 12/01030101 5060497840041 | Medical electric suction unit static with UK Plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 12/01030102/ 5060497840058 | Medical electric suction unit mobile with UK Plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 12/01030501/ 5060497840065 | Medical electric suction unit static with EU plug, 1x2L ABBOTT disposable liner system. | 63648/A0601010201 |
| SAM 12/01030502/ 5060497840072 | Medical electric suction unit mobile with EU plug, 1x2L ABBOTT disposable liner system. | 63648/A0601010201 |
| SAM 12/01060101/ 5060497840089 | Medical electric suction unit static with UK plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 12/01060102/ 5060497840096 | Medical electric suction unit mobile with UK Plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 12/01060501/ 5060497840102 | Medical electric suction unit static with EU plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 12/01060502/ 5060497840119 | Medical electric suction unit mobile with EU plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 12/01070101/ 5060497840126 | Medical electric suction unit static with UK Plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 12/01070102/ 5060497840133 | Medical electric suction unit mobile with UK Plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 12/01070501/ 5060497840140 | Medical electric suction unit static with EU plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 12/01070502/ 5060497840157 | Medical electric suction unit mobile with EU plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 12/01110101/ 5060497840164 | Medical electric suction unit static with UK plug, 1x1.5L VACUSAFE collection jar | 63648/A0601010201 |
| SAM 12/03010501/ 5060497840171 | Medical electric suction unit static with EU plug & 4m cable, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 12/03010502/ 5060497840188 | Medical electric suction unit mobile with EU plug & 4m cable, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 12/03070101/ 5060497840195 | Medical electric suction unit static with UK plug & 4m cable, 1x2L SERRES disposable liner system | 63648/A0601010201 |

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| SAM 12/03070102/ 5060497840201 | Medical electric suction unit mobile with UK plug & 4m cable, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 12/03070501/ 5060497840218 | Medical electric suction unit static with EU plug & 4m cable, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 12/03070502/ 5060497840225 | Medical electric suction unit mobile with EU plug & 4m cable, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 12/KSMEDELA/ 5060497840232 | Medical electric suction unit static with UK plug, 1x2L MEDELA collection jar | 63648/A0601010201 |
| SAM 12/01010602/ 5060497840249 | Medical electric suction unit mobile with AUS/NZ plug, 1x2L reusable SAM2 plastic jar | 63648/A0601010201 |
| SAM 12/01030602/ 5060497840256 | Medical electric suction unit mobile with AUS/NZ plug, 1x2L reusable ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 12/01140701/ 5060497840263 | Medical electric suction unit static with USA plug, 1x2L PERGO disposable liner system | 63648/A0601010201 |
| SAM 12X/01010101/ 5060497840270 | Medical electric suction unit static for laboratory use with pump tube bypass, UK plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM MS/01010101/ 5060497840317 | Medical electric micro suction unit static with UK plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM MS/01010102/ 5060497840324 | Medical electric micro suction unit mobile with UK plug,1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM MS/01030101/ 5060497840331 | Medical electric micro suction unit static with UK plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM MS/01030102/ 5060497840348 | Medical electric micro suction unit mobile with UK plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM MS/01060101/ 5060497840355 | Medical electric micro suction unit static with UK plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM MS/01060102/ 5060497840362 | Medical electric micro suction unit mobile with UK plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM MS/01070101 5060497840379 | Medical electric micro suction unit static with UK plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM MS/01070102/ 5060497840386 | Medical electric micro suction unit mobile with UK plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM MS/01140701/ 5060497840393 | Medical electric micro suction unit mobile with USA plug, 1x2L PERGO disposable liner system | 63648/A0601010201 |
| SAM 14/01010101/ 5060497840508 | Medical electric suction unit static with UK plug, 2x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 14/01010102/ 5060497840515 | Medical electric suction unit mobile with UK plug, 2x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 14/01010501/ 5060497840522 | Medical electric suction unit static with EU plug, 2x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 14/01010502/ 5060497840539 | Medical electric suction unit mobile with EU plug, 2x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |

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| SAM 14/01030101/ 5060497840546 | Medical electric suction unit static with UK Plug, 2x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 14/01030102/ 5060497840553 | Medical electric suction unit mobile with UK Plug, 2x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 14/01030501/ 5060497840560 | Medical electric suction unit static with EU plug, 2x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 14/01030502/ 5060497840577 | Medical electric suction unit mobile with EU plug, 2x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 14/01060101/ 5060497840584 | Medical electric suction unit static with UK plug, 2x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 14/01060102/ 5060497840591 | Medical electric suction unit mobile with UK plug, 2x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 14/01060501/ 5060497840607 | Medical electric suction unit static with EU plug, 2x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 14/01060502/ 5060497840614 | Medical electric suction unit mobile with EU plug, 2x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 14/01070101/ 5060497840621 | Medical electric suction unit static with UK plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 14/01070102/ 5060497840638 | Medical electric suction unit mobile with UK plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 14/01070501/ 5060497840645 | Medical electric suction unit static with EU plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 14/01070502/ 5060497840652 | Medical electric suction unit mobile with EU plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 14/01140701/ 5060497840669 | Medical electric suction unit static with USA plug, 2x2L PERGO disposable liner system | 63648/A0601010201 |
| SAM 14/03060102/ 5060497840676 | Medical electric suction unit mobile with UK plug &5m cable, 2x2L VACSAX disposable liner system. | 63648/A0601010201 |
| SAM 14X/01010101/ 5060497840683 | Medical electric suction unit static for laboratory use with pump tube bypass, UK plug, 2x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 15/01010101/ 5060497841000 | Medical electric suction unit for Intra Uterine use static with UK plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 15/01010102/ 5060497841017 | Medical electric suction unit for Intra Uterine use mobile with UK plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 15/01010501/ 5060497841024 | Medical electric suction unit for Intra Uterine use static with EU plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 15/01010502/ 5060497841031 | Medical electric suction unit for Intra Uterine use mobile with EU plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 15/01030101/ 5060497841048 | Medical electric suction unit for Intra Uterine use static with UK plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 15/01030102/ 5060497841055 | Medical electric suction unit for Intra Uterine use mobile with UK plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |

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| SAM 15/01030501/ 5060497841062 | Medical electric suction unit for Intra Uterine use static with EU plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 15/01030502/ 5060497841079 | Medical electric suction unit for Intra Uterine use mobile with EU plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 15/01060101/ 5060497841086 | Medical electric suction unit for Intra Uterine use static with UK plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 15/01060102/ 5060497841093 | Medical electric suction unit for Intra Uterine use mobile with UK plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 15/01060501/ 5060497841109 | Medical electric suction unit for Intra Uterine use static with EU plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 15/01060502/ 5060497841116 | Medical electric suction unit for Intra Uterine use mobile with EU plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 15/01070101/ 5060497841123 | Medical electric suction unit for Intra Uterine use static with UK plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 15/01070102/ 5060497841130 | Medical electric suction unit for Intra Uterine use mobile with UK plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 15/01070501/ 5060497841147 | Medical electric suction unit for Intra Uterine use static with EU plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 15/01070502/ 5060497841154 | Medical electric suction unit for Intra Uterine use mobile with EU plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 15/01140701/ 5060497841161 | Medical electric suction unit for Intra Uterine use static with USA plug, 1x2L PERGO disposable liner system | 63648/A0601010201 |
| SAM 16/01010101/ 5060497841253 | Medical electric suction unit for Intra Uterine use static with UK plug, 2x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 16/01010102/ 5060497841260 | Medical electric suction unit for Intra Uterine use mobile with UK plug, 2x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 16/01010501/ 5060497841277 | Medical electric suction unit for Intra Uterine use static with EU plug, 2x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 16/01010502/ 5060497841284 | Medical electric suction unit for Intra Uterine use mobile with EU plug, 2x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 16/01030101/ 5060497841291 | Medical electric suction unit for Intra Uterine use static with UK plug, 2x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 16/01030102/ 5060497841307 | Medical electric suction unit for Intra Uterine use mobile with UK plug, 2x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 16/01030501/ 5060497841314 | Medical electric suction unit for Intra Uterine use static with EU plug, 2x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 16/01030502/ 5060497841321 | Medical electric suction unit for Intra Uterine use mobile with EU plug, 2x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 16/01060101/ 5060497841338 | Medical electric suction unit for Intra Uterine use static with UK plug, 2x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 16/01060102/ 5060497841345 | Medical electric suction unit for Intra Uterine use mobile with UK plug, 2x2L VACSAX disposable liner system | 63648/A0601010201 |

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| SAM 16/01060501/ 5060497841352 | Medical electric suction unit for Intra Uterine use static with EU plug, 2x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 16/01060502/ 5060497841369 | Medical electric suction unit for Intra Uterine use mobile with EU plug, 2x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 16/01070101/ 5060497841376 | Medical electric suction unit for Intra Uterine use static with UK plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 16/01070102/ 5060497841383 | Medical electric suction unit for Intra Uterine use mobile with UK plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 16/01070501/ 5060497841390 | Medical electric suction unit for Intra Uterine use static with EU plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 16/01070502/ 5060497841406 | Medical electric suction unit for Intra Uterine use mobile with EU plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 16/01140701/ 5060497841413 | Medical electric suction unit for Intra Uterine use static with USA plug, 2x2L PERGO disposable liner system | 63648/A0601010201 |
| SAM 17T/01010101/ 5060497841505 | Medical electric suction unit for Thoracic Drainage static with UK plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 17T/01010102/ 5060497841512 | Medical electric suction unit for Thoracic Drainage mobile with UK plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 17T/01010501/ 5060497841529 | Medical electric suction unit for Thoracic Drainage static with EU plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 17T/01010502/ 5060497841536 | Medical electric suction unit for Thoracic Drainage mobile with EU plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 17T/01030101/ 5060497841543 | Medical electric suction unit for Thoracic Drainage static with UK plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 17T/01030102/ 5060497841550 | Medical electric suction unit for Thoracic Drainage mobile with UK plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 17T/01030501/ 5060497841567 | Medical electric suction unit for Thoracic Drainage static with EU plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 17T/01030502/ 5060497841574 | Medical electric suction unit for Thoracic Drainage mobile with EU plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 17T/01060101/ 5060497841581 | Medical electric suction unit for Thoracic Drainage static with UK plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 17T/01060102/ 5060497841598 | Medical electric suction unit for Thoracic Drainage mobile with UK plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 17T/01060501/ 5060497841604 | Medical electric suction unit for Thoracic Drainage static with EU plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 17T/01060502/ 5060497841611 | Medical electric suction unit for Thoracic Drainage mobile with EU plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 17T/01070101/ 5060497841628 | Medical electric suction unit for Thoracic Drainage static with UK plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 17T/01070102/ 5060497841635 | Medical electric suction unit for Thoracic Drainage mobile with UK plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 17T/01070501/ 5060497841642 | Medical electric suction unit for Thoracic Drainage static with EU plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |

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| SAM 17T/01070502/ 5060497841659 | Medical electric suction unit for Thoracic Drainage mobile with EU plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 17T/01140701/ 5060497841666 | Medical electric suction unit for Thoracic Drainage static with USA plug, 1x2L PERGO disposable liner system | 63648/A0601010201 |
| SAM 17W/01010101/ 5060497841758 | Medical electric suction unit for Thoracic Drainage static with UK plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 17W/01010102/ 5060497841765 | Medical electric suction unit for Thoracic Drainage mobile with UK plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 17W/01010501/ 5060497841772 | Medical electric suction unit for Thoracic Drainage static with EU plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 17W/01010502/ 5060497841789 | Medical electric suction unit for Thoracic Drainage mobile with EU plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 17W/01030101/ 5060497841796 | Medical electric suction unit for Thoracic Drainage static with UK plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 17W/01030102/ 5060497841802 | Medical electric suction unit for Thoracic Drainage mobile with UK plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 17W/01030501/ 5060497841819 | Medical electric suction unit for Thoracic Drainage static with EU plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 17W/01030502/ 5060497841826 | Medical electric suction unit for Thoracic Drainage mobile with EU plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 17W/01060101/ 5060497841833 | Medical electric suction unit for Thoracic Drainage static with UK plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 17W/01060102/ 5060497841840 | Medical electric suction unit for Thoracic Drainage mobile with UK plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 17W/01060501/ 5060497841857 | Medical electric suction unit for Thoracic Drainage static with EU plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 17W/01060502/ 5060497841864 | Medical electric suction unit for Thoracic Drainage mobile with EU plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 17W/01070101/ 5060497841871 | Medical electric suction unit for Thoracic Drainage static with UK plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 17W/01070102/ 5060497841888 | Medical electric suction unit for Thoracic Drainage mobile with UK plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 17W/01070501/ 5060497841895 | Medical electric suction unit for Thoracic Drainage static with EU plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 17W/01070502/ 5060497841901 | Medical electric suction unit for Thoracic Drainage mobile with EU plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 17W/01140701/ 5060497841918 | Medical electric suction unit for Thoracic Drainage static with USA plug, 1x2L PERGO disposable liner system | 63648/A0601010201 |
| SAM 18/01010101/ 5060497841987 | Medical electric suction unit static with UK plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 18/01010102/ 5060497841994 | Medical electric suction unit mobile with UK plug, 1x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 18/01010501/ 5060497842007 | Medical electric suction unit static with EU plug, 1x2L reusable plastic collection jar | 63648/A0601010201 |

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| SAM 18/01010502/ 5060497842014 | Medical electric suction unit mobile with EU plug, 1x2L reusable plastic collection jar | 63648/A0601010201 |
| SAM 18/01030101/ 5060497842021 | Medical electric suction unit static with UK Plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 18/01030102/ 5060497842038 | Medical electric suction unit mobile with UK Plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 18/01030501/ 5060497842045 | Medical electric suction unit static with EU Plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 18/01030502/ 5060497842052 | Medical electric suction unit mobile with EU Plug, 1x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 18/01060101/ 5060497842069 | Medical electric suction unit static with UK plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 18/01060102/ 5060497842076 | Medical electric suction unit mobile with UK plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 18/01060501/ 5060497842083 | Medical electric suction unit static with EU plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 18/01060502/ 5060497842090 | Medical electric suction unit mobile with EU plug, 1x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 18/01070101/ 5060497842106 | Medical electric suction unit static with UK Plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 18/01070102/ 5060497842113 | Medical electric suction unit mobile with UK Plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 18/01070501/ 5060497842120 | Medical electric suction unit static with EU Plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 18/01070502/ 5060497842137 | Medical electric suction unit mobile with EU Plug, 1x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 18/01140701/ 5060497842144 | Medical electric suction unit static with USA plug, 1x2L PERGO disposable liner system | 63648/A0601010201 |
| SAM 19/01010101/ 5060497842250 | Medical electric suction unit static with UK plug, 2x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 19/01010102/ 5060497842267 | Medical electric suction unit mobile with UK plug, 2x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 19/01010501/ 5060497842274 | Medical electric suction unit static with EU plug, 2x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 19/01010502/ 5060497842281 | Medical electric suction unit mobile with EU plug, 2x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 19/01030101/ 5060497842298 | Medical electric suction unit static with UK Plug, 2x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 19/01030102/ 5060497842304 | Medical electric suction unit mobile with UK Plug, 2x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 19/01030501/ 5060497842311 | Medical electric suction unit static with EU Plug, 2x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 19/01030502/ 5060497842328 | Medical electric suction unit mobile with EU Plug, 2x2L ABBOTT disposable liner system | 63648/A0601010201 |

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| SAM 19/01060101/ 5060497842335 | Medical electric suction unit static with UK plug, 2x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 19/01060102/ 5060497842342 | Medical electric suction unit mobile with UK plug, 2x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 19/01060501/ 5060497842359 | Medical electric suction unit static with EU plug, 2x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 19/01060502/ 5060497842366 | Medical electric suction unit mobile with EU plug, 2x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 19/01070101/ 5060497842373 | Medical electric suction unit static with UK Plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 19/01070102/ 5060497842380 | Medical electric suction unit mobile with UK Plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 19/01070501/ 5060497842397 | Medical electric suction unit static with EU Plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 19/01070502/ 5060497842403 | Medical electric suction unit mobile with EU Plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 19/01140701/ 5060497842410 | Medical electric suction unit static with USA plug, 2x2L PERGO disposable liner system | 63648/A0601010201 |
| SAM 35/01010102/ 5060497842502 | Medical electric suction unit mobile with UK Plug, 2x2L reusable SAM2 plastic collection jars | 63648/A0601010201 |
| SAM 35/01010502/ 5060497842519 | Medical electric suction unit mobile with EU Plug, 2x2L reusable SAM2 plastic collection jar | 63648/A0601010201 |
| SAM 35/01030102/ 5060497842526 | Medical electric suction unit mobile with UK Plug, 2x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 35/01030502/ 5060497842533 | Medical electric suction unit mobile with EU Plug, 2x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 35/01060102/ 5060497842540 | Medical electric suction unit mobile with UK Plug, 2x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 35/01060502/ 5060497842557 | Medical electric suction unit mobile with EU Plug, 2x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 35/01070102/ 5060497842564 | Medical electric suction unit mobile with UK Plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 35/01070502/ 5060497842571 | Medical electric suction unit mobile with EU Plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 35/01050102/ 5060497842588 | Medical electric suction unit mobile with UK Plug, 2x4L reusable plastic collection jars | 63648/A0601010201 |
| SAM 35/01050502/ 5060497842595 | Medical electric suction unit mobile with EU Plug, 2x4L reusable plastic collection jars | 63648/A0601010201 |
| SAM 35/03030102/ 5060497842618 | Medical electric suction unit mobile with UK Plug & 5m cable, 2x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 35/03060102/ 5060497842625 | Medical electric suction unit mobile with UK Plug & 5m cable, 2x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 35/03070102/ 5060497842632 | Medical electric suction unit mobile with UK Plug & 5m cable, 2x2L SERRES disposable liner system | 63648/A0601010201 |

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| SAM 35/03070502/ 5060497842649 | Medical electric suction unit mobile with EU Plug & 5m cable, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 35/01070101/ 5060497842656 | Medical electric suction unit static with UK Plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 35/01140702/ 5060497842663 | Medical electric suction unit mobile with USA plug, 2x2L PERGO disposable liner system | 63648/A0601010201 |
| SAM 35Q/01000101/ 5060497842670 | Medical electric suction unit static with UK Plug & no collection jars | 63648/A0601010201 |
| SAM 35Q/01060101/ 5060497842687 | Medical electric suction unit static with UK Plug, 2x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 35Q/01070701/ 5060497842694 | Medical electric suction unit static with UK Plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 36/01010102/ 5060497843004 | Medical electric suction unit mobile with UK Plug, 2x2L reusable SAM2 plastic collection jars | 63648/A0601010201 |
| SAM 36/01010502/ 5060497843011 | Medical electric suction unit mobile with EU Plug, 2x2L reusable SAM2 plastic collection jars | 63648/A0601010201 |
| SAM 36/01030102/ 5060497843028 | Medical electric suction unit mobile with UK Plug, 2x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 36/01030502/ 5060497843035 | Medical electric suction unit mobile with EU Plug, 2x2L ABBOTT disposable liner system | 63648/A0601010201 |
| SAM 36/01060102/ 5060497843042 | Medical electric suction unit mobile with UK Plug, 2x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 36/01060502/ 5060497843059 | Medical electric suction unit mobile with EU Plug, 2x2L VACSAX disposable liner system | 63648/A0601010201 |
| SAM 36/01070102/ 5060497843066 | Medical electric suction unit mobile with UK Plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 36/01070502/ 5060497843073 | Medical electric suction unit mobile with EU Plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 36/01070101/ 5060497843080 | Medical electric suction unit static with UK Plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 36/01070501/ 5060497843097 | Medical electric suction unit static with EU Plug, 2x2L SERRES disposable liner system | 63648/A0601010201 |
| SAM 36/01140702/ 5060497843103 | Medical electric suction unit mobile with USA plug, 2x2L PERGO disposable liner system | 63648/A0601010201 |

## Change Table

| Date of Change | Description of Change | Signature |
|---|---|---|
| 30/06/2025 | 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 60601-1:2006 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance<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 10079-4:2021 – Medical suction equipment – Part 4: General requirements<br>• EN 60601-1:2006+A1:2013 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance |  |
| 16/10/2025 | Added EN 20417:2021 Standard to the list of Applicable Standards (EN ISO 20417:2021 – Medical devices – Information to be supplied by the manufacturer) |  |
| 22/10/2025 | Re-issue of Version 3 in the correct format, including an addendum documenting the applicable standards and changes associated with the transition from MDD to MDR. The original Declaration of Conformity (Version 1) remains unchanged. |  |
| 20/10/2026 | Updated Appendix II – Product Listing/Schedule to expand the previous single general product entry into individual listings for **159** SAM Electric Powered Suction 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 | 30/06/2025 | Updated the list of Applicable 'harmonized' standards based on the latest versions under MDD 93/42/EEC. |
| 3.0 | G. M. Martin | 16/10/2025 | Added EN 20417:2021 Standard to the list of Applicable Standards |
| 4.0 | G. M. Martin | 22/10/2025 | Re-issue of Version 3 in correct format adding addendum document for applicable standards and changes in line with MDD-to-MDR transition, without revising the original DOC (Version 1). |
| 5.0 | 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. |