Declaration of Conformity

for **SAM Electric & Battery 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 & Battery 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
EN 1789:2020	Medical vehicles and their equipment – Road Ambulances

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
SAM EPS	Single Bottle High Vacuum & Flow Battery Suction Unit	36777

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 Electric & Battery 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 1789:2020+A1:2023	Medical vehicles and their equipment – Road Ambulances
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
EN 1789:2020	Medical vehicles and their equipment – Road Ambulances

Appendix II – Product Listing/Schedule

Catalogue Number/UDI-DI	Description/Name	GMDN/EMDN Code
SAMeps/01020101/ 5060497844551	Medical emergency battery & mains portable standard suction unit with UK plug, 1x 1L reusable SAM1 plastic collection jar	63648/A0601010201
SAMeps/01020501/ 5060497844568	Medical emergency battery & mains portable standard suction unit with EU plug, 1x 1L reusable SAM1 plastic collection jar	63648/A0601010201
SAMeps/01030101/ 5060497844575	Medical emergency battery & mains portable standard suction unit with UK plug, 1x 1L ABBOTT disposable liner system	63648/A0601010201
SAMeps/01030501/ 5060497844582	Medical emergency battery & mains portable standard suction unit with EU plug, 1x 1L ABBOTT disposable liner system	63648/A0601010201
SAMeps/01060101/ 5060497844599	Medical emergency battery & mains portable standard suction unit with UK plug, 1x 1L VACSAX disposable liner system	63648/A0601010201
SAMeps/01060501/ 5060497844605	Medical emergency battery & mains portable standard suction unit with EU plug, 1x 1L VACSAX disposable liner system	63648/A0601010201
SAMeps/01070101/ 5060497844612	Medical emergency battery & mains portable standard suction unit with UK plug, 1x 1L SERRES disposable liner system	63648/A0601010201
SAMeps/01070501/ 5060497844629	Medical emergency battery & mains portable standard suction unit with EU plug, 1x 1L SERRES disposable liner system	63648/A0601010201
SAMeps/01020102/ 5060497844636	Medical emergency battery & mains portable neonatal suction unit with UK plug, 1x 1L reusable SAM1 plastic collection jar	63648/A0601010201
SAMeps/01020502/ 5060497844643	Medical emergency battery & mains portable neonatal suction unit with EU plug, 1x 1L reusable SAM1 plastic collection jar	63648/A0601010201
SAMeps/01030102/ 5060497844650	Medical emergency battery & mains portable neonatal suction unit with UK plug, 1x 1L ABBOTT disposable liner system	63648/A0601010201
SAMeps/01030502/ 5060497844667	Medical emergency battery & mains portable neonatal suction unit with EU plug, 1x 1L ABBOTT disposable liner system	63648/A0601010201
SAMeps/01060102/ 5060497844674	Medical emergency battery & mains portable neonatal suction unit with UK plug, 1x 1L VACSAX disposable liner system	63648/A0601010201
SAMeps/01060502/ 5060497844681	Medical emergency battery & mains portable neonatal suction unit with EU plug, 1x 1L VACSAX disposable liner system	63648/A0601010201
SAMeps/01070102/ 5060497844698	Medical emergency battery & mains portable neonatal suction unit with UK plug, 1x 1L SERRES disposable liner system	63648/A0601010201
SAMeps/01070502/ 5060497844704	Medical emergency battery & mains portable neonatal suction unit with EU plug, 1x 1L SERRES disposable liner system	63648/A0601010201
SAMeps/01060601/ 5060497844711	Medical emergency battery & mains portable standard suction unit with AUS/NZ plug, 1x 1L reusable ABBOTT disposable liner system	63648/A0601010201

SAMeps/01140701/ 5060497844728	Medical emergency battery & mains portable standard suction unit with USA plug, 1x 1L PERGO disposable liner system	63648/A0601010201

Change Table

Date of Change	Description of Change	Signature
16/10/2025	The following standards have been removed from the applicable standards list: • 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 • EN 1789:2020 – Medical vehicles and their equipment – Road ambulances The following updated and additional standards have been added to the applicable standards list: • 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 1789:2020+A1:2023 – Medical vehicles and their equipment – Road ambulances • EN ISO 20417:2021 – Medical devices – Information to be supplied by the manufacturer	
19/10/2026	Updated Appendix II – Product Listing/Schedule to expand the previous single general product entry into individual listings for **18** SAM Electric & Battery 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	16/10/2025	Updated the list of applicable standards based on the latest versions.
3.0	G. M. Martin	19/10/2026	Addendum to DOC – Updated Appendix II Product Listing/Schedule to include Catalogue Number/UDI-DI, Description/Name and GMDN/EMDN Code.