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