Declaration of Conformity

for **SAM Suction Filters**

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	SAM Suction Filters
Legal Manufacturer: (Name on Label)	M. G. Electric (Colchester) Ltd, Unit 5 Altbarn Close, Wyncolls Road, Colchester, Essex, CO4 9HY, United Kingdom
Manufacturers SRN:	Not Yet Available
Basic UDI-DI:	506049784AA005V
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	In-line Filter for use with Suction Devices
MDR Classification:	Class I
Notified Body:	Not Applicable for Class I
EC Certificate:	Not Applicable for Class I
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	**MT-AR-000000234**
Medical Device Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745.

Name G. M. Martin **Position** Managing Director

Signed G.M.Mart **Date** 22/04/2022

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 (CS):

Standard/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012 / ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – General requirements
EN ISO 20417:2021	Medical Devices – Information to be supplied by the manufacturer
EN ISO 10079-1:2015	Medical Suction Equipment Part 1 Electrically powered suction equipment

Appendix II – Product Listing/Schedule

UDI-DI	Description/Name	GMDN / EMDN Code
5060497847514	MSP1002 (01-0199) SAM Bacterial In-line Filter	37798 / A04010199
5060497847521	MSP1003 (01-0200) SAM Hydrophobic & Bacterial In-line Filter	37798 / A04010199

Version History

Version	Compiled by	Date	Description
1.0	G. M. Martin	30/10/2020	First issue including EU Representative Advena
2.0	G. M. Martin	15/02/2022	Compliance to MDR 2017/745
2.1	G. M. Martin	22/04/2022	Changed Appendix II table title to UDI-DI & corrected EMDN Codes