Declaration of Conformity

for **SAM 2 Collection Containers**

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 2 Collection Containers
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:	Collection Bottle for use with Suction unit for the aspiration of body fluids and fluids in general
MD Directive Classification:	Class I Measuring
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** 22/10/2025

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

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
SAM 2	2 Litre Collection Container for Suction Unit	38476
SAM 2 IU	2 Litre Collection Container for Suction Unit for IU Procedures	38476

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	09/10/2025	Updating standard EN ISO 13485 to include amendment
3.0	G. M. Martin	22/10/2025	Re-issue of Version 2 in correct format adding addendum document for applicable standards in line with MDD-to-MDR transition, without revising the original DOC

Declaration of Conformity Addendum

for **SAM 2 Collection Containers**

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.

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 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

Details of Addendum Changes:

Version	Compiled by	Date	Description
3.0	G. M. Martin	22/10/2025	• Updating standard EN ISO 13485 to include amendment A11:2021 • Adding EN ISO10079-4 which specifies general requirements for medical suction equipment applicable to this device. • Replaced EN 1041:2008 with EN ISO 20417:2021 because EN 1041 has been superseded it's now officially withdrawn from the list of harmonized standards under both MDD and MDR.