# EC DECLARATION OF CONFORMITY

Issue 7

**Scope –** This declaration of conformity covers the electrically actuated medical suction equipment:

**SAM12, SAM14, SAM15, SAM 16, SAM17T, SAM17W, SAM18, SAM19, SAM35, SAM36, SAM420, SAM427**

**Applied Directives and Standards –**

- EC Medical Device Directive 93/42/EEC as amended by 2007/47/EC (M5)
- Recast Directive on the Restriction of Hazardous Substances in Electrical and Electronic Equipment 2011/65/EU (RoHS 2)
- BS EN 60601-1:2006
- BS EN 60601-1-2:2007
- BS EN ISO 10079-1:2009
- GMDN 36777

We MG Electric (Colchester) Ltd as manufacturer of medical suction equipment, declare that our electrically actuated medical suction group of products has been classified as Class IIa in accordance with Annex IX Rule 11 and meet the essential requirements and provisions which apply to them as defined in Article 3 and 11 and as set out in Annex I of the EC Medical Device Directive 93/42/EEC.

We operate a Quality System in accordance with BS EN ISO 9001: 2008 and BS EN ISO 13485: 2012 standards. We have demonstrated compliance with Annex V (Production Quality Assurance) and Annex VII of the EC Medical Device Directive 93/42/EEC and we have appointed British Standards Institute as our Notified Body to provide certification services as required by the Medical Device Directive. As such we are entitled to use the CE0086 licence mark as shown below.

CE
0086

*Signed for and on behalf of:*
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Date: 14th October 2015