

# MGE

## EC DECLARATION OF CONFORMITY

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

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

**Applied Directives and Standards –**

- EC Medical Device Directive 93/42/EEC
- BS EN 60601-1:2006
- BS EN 60601-1-2:2007
- BS EN ISO 10079-1:2009

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 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 : 2003 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.



*Signed for and on behalf of:*  
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A handwritten signature in red ink, appearing to read 'G. M. Martin', written over a horizontal line.

Graham Martin  
Managing Director

Date: 4<sup>th</sup> January 2010