

# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

**No.** CE 01938  
**Issued To:** M G Electric (Colchester) Ltd  
Wyncolls Road  
Colchester  
CO4 9HY  
United Kingdom

In respect of:

**The manufacture of medical suction units.  
Those aspects of Annex V concerned with the metrological requirements of Fluid Collection Vessel.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1998-06-04**

Date: **2021-01-05**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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## Supplementary Information to CE 01938

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NBOG code(s)	Device description	Intended purpose
<b>Class IIa</b>		
MD 1104	Medical Suction Unit	NA for class IIa devices
MD 1104	Pipeline Vacuum Regulator	NA for class IIa devices
<b>Class Im</b>		
MD 0104	Fluid Collection Vessel	NA for class Im devices

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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**Colchester**  
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**United Kingdom**

**Subcontractor:**

**Service(s) supplied**

Advena Ltd  
Tower Business Centre, 2nd Flr,  
Tower Street, Swatar, BKR 4013  
Malta

**EU Representative**

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# EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 01938**  
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Date	Reference Number	Action
04 June 1998		First issue.
14 January 2005		New certificate format - Certificate renewal.
06 January 2010	7465451	Certificate renewal.
23 December 2014	8225007	Certificate renewal.
20 February 2019	7780193	Traceable to NB 0086.
10 January 2020	9756456	Renewal - Added device table Updated and clarified scope to include existing Class Im device
Current	3342530	Added EU rep 'Advena Ltd'.