By Royal Charter

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: **2020-01-10** 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.

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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Supplementary Information to CE 01938

Issued To:

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

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 01938**
Date: **2020-01-10**
Issued To: **M G Electric (Colchester) Ltd**
Wyncolls Road
Colchester
CO4 9HY
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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.
Current	9756456	Renewal - Added device table Updated and clarified scope to include existing Class Im device

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MG Electric (Colchester) Ltd
Wyncolls Road
Colchester, Essex
CO4 9HY
United Kingdom

26th October 2023

Notified Body Confirmation Letter

Reference: EU2023-607/715074

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

MG Electric (Colchester) Ltd
Wyncolls Road
Colchester, Essex
CO4 9HY
United Kingdom

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

NB 2797

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
SAM Electric & Battery Powered Suction Units **506049784AA025Z**	Class IIa	N/A	CE 01938, May 26, 2024, NB# 2797
SAM Electric Powered Suction Units **506049784AA0465**	Class IIa	N/A	CE 01938, May 26, 2024, NB# 2797
SAM Vacuum Powered Suction Regulators **506049784AA0363**	Class IIa	N/A	CE 01938, May 26, 2024, NB# 2797
SAM Collection Containers **506049784AA015X**	Class IIa	N/A	CE 01938, May 26, 2024, NB# 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/10/26	Initial issue

NB 2797