

EC Certificate Full Quality Assurance System: Certificate GB19/964711

The management system of  
**MEC Medical Limited**

Unit 3, Trust Estate, Wilbury Way, Hitchin, Hertfordshire, SG4 0UZ, UK

has been assessed and certified as meeting the requirements of

**Directive 93/42/EEC**  
on medical devices, Annex II (excluding Section 4)

For the following products

**Medical Gas System Components:**

- Hose assemblies and Associated Fittings
- Purair AGSS Systems
- Medical gas Terminal units
- Gas specific Schrader units
- Ambulance change over valves
- Medical Gas regulators
- Medical Gas Flowmeters

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 18 May 2021 until 14 June 2023 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 14 June 2005

Certification is based on reports numbered GB/PC 210478

Authorised by

Global Medical Devices Head of Notified Body

**SGS Belgium NV, Notified Body 1639**

SGS House Noorderlaan 87 2030 Antwerp Belgium  
t +32 (0)3 545 48 48 f +32 (0)3 545 48 49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4, EN rev. 02

Page 1 of 1



This document is a Web version of SGS certificate for electronic use exclusively. It shall only be available by clicking on SGS Certification Mark which has been posted on Your website. It shall not be printed in anyway. This document is copyright protected. No content or appearance may be reproduced without the express written permission of SGS. Any misuse, alteration, forgery or falsification is unlawful.

**Supplementary information to AR120 817978**

*Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3*

Issued to:

MEC Medical Limited

Unit 3, Trust Estate, Wilbury Way, Hitchin, Hertfordshire, SG4 0UZ, UK

**Date:** 16 October 2024

**Changes Approved:**

Date	Reference Number	Action
16 October 2024	30286632	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Change Over Valve, Medical Gas Regulator, Medical Gas Flowmeter, Medical Gas Hose Assembly, Gas Specific Schrader Adapter, PurAir AGSS System, Medical Gas Terminal Unit. Change of address from Unit 3, Trust Estate, Wilbury Way, Hitchin, Hertfordshire, SG4 0UZ, UK to MEC House, 8 Fountain Drive, Hertford, Hertfordshire, SG13 7UB, United Kingdom. Original NB Certificate Number: GB19/964711

16 October 2024

MEC Medical Limited  
 MEC House  
 8 Fountain Drive  
 Hertford  
 Hertfordshire  
 SG13 7UB  
 United Kingdom

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) (as amended by (EU) 2023/607) and as per the guidance provided in MDCG 2020-3.

The related MDD certificate specified below remains valid until the expiry date stated on the certificate or until the end of the transition period as specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), subject to the manufacturer's continued compliance to the other conditions provided in Article 120(3c) of MDR (as amended by (EU) 2023/607).

Original Certificate Number	BSI Reference Number	Directive and Annex	Reference Number	Changes approved
GB19/964711	AR120 817978	93/42/EEC Annex II excluding Section 4	30286632	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Change Over Valve, Medical Gas Regulator, Medical Gas Flowmeter, Medical Gas Hose Assembly, Gas Specific Schrader Adapter, PurAir AGSS System, Medical Gas Terminal Unit. Change of address from Unit 3, Trust Estate, Wilbury Way, Hitchin, Hertfordshire, SG4 0UZ, UK to MEC House, 8 Fountain Drive, Hertford, Hertfordshire, SG13 7UB, United Kingdom. Original NB Certificate Number: GB19/964711

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Graeme Tunbridge  
 Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.  
 Say Building  
 John M. Keynesplein 9  
 1066 EP Amsterdam  
 The Netherlands

T: +31 20 346 0780  
 info.nl@bsigroup.com  
 bsigroup.nl