

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.

Validity extended to 31 Dec 2028

See page 2 for MDR Article 120

Extension Confirmation

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

LPM5007 - Certificate CE1639 Annex II-4, EN rev. 02

Page 1 of 1



EU MDR Article 120 Extension Confirmation

Manufacturer Details

Manufacturer Name:	MEC Medical Limited
Manufacturer Address:	MEC House, 8 Fountain Drive, Hertford, Hertfordshire, SG13 7UB, United Kingdom
EC Representative:	MEC Medical Limited, Ground Floor, 71 Lower Baggot Street, Dublin 2, D02 P593

MEC declare that the CE Certificate listed below was issued under the EU Medical Devices Directive (93/42/EEC) on or after 25 May 2017 and was still valid on 26 May 2021 and the conditions for extension of the validity of the CE Certificate under the EU Medical Devices Regulation (2017/745) Article 120 set out below have been met in relation to the CE Certificates listed.

CE Certificate Details

CE Certificate Number	Notified Body	Expiry Date	Extended Validity
GB19/964711	SGS Belgium NV / 1639	14/06/2023	31/12/2028

For and on behalf of MEC Medical Limited:

Signed:



Name:

Eoin Riggs

Title:

Quality Manager

Date:

20/03/2023