

The management system of

eVent Medical Ltd

60 Empire Drive, Lake Forest, CA, 92630, United States

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

INSPIRATION™ ventilators for continuous respiratory support in an acute and sub-acute institutional healthcare environment, EVOLUTION™ ventilators for continuous ventilation for patients requiring respiratory support.

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 13 June 2018 until 10 February 2023 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 10 February 2021 Issue 16. Certified since 05 October 2000

Certification is based on reports numbered WW/MW 201252

Authorised by



SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0215

Page 1 of 1





Certificate US00/52067



The management system of

eVent Medical Ltd

60 Empire Drive, Lake Forest, CA, 92630, United States

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

Design, manufacture, servicing and distribution of INSPIRATION™ LS, 5i, and 7i ventilators and EVOLUTION™ 3e ventilators.

This certificate is valid from 13 June 2018 until 10 February 2021 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 10 February 2021 Issue 17. Certified since 05 October 2000

Expiry date of last certificate: 10 February 2018 End date of last recertification audit: 02 March 2018

Authorised by

#P

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sqs.com

HC SGS 13485 2016 0118

Page 1 of 1









This document is issued by the Company subject to its General Conditions of Certification Services accessible at wew sps.com/terms, and conditions.htm. Attenden is crown to the limitations of fishtity, Indemnification and jurisdictions issues established therein. The authenticity of this document may be verified at http://www.sps.com/en/certified-dients-and-products/certified-dient-directory. Any unsubminged electricin, proper or falletisets of the octinator or speciation of this document is unlawful and offenders may be prosecuted to the fullest