

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

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SGS CE 02 0215

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Certificate US00/52067

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## 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



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