

Certificate US15/842156



The management system of

Hadleigh Health Technologies, LLC

30 Castro Avenue,
San Rafael, CA, 94901, United States

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016



For the following activities

Design and development, manufacture, servicing, and distribution of bubble continuous positive airway pressure device (bCPAP), patient tubing, nasal prongs and connectors for paediatric use.

This certificate is valid from 16 July 2018 until 12 May 2021
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 03 March 2021

Issue 2. Certified since 12 May 2015

Expiry date of last certificate: 12 May 2018

End date of last recertification audit: 24 May 2018

Authorised by

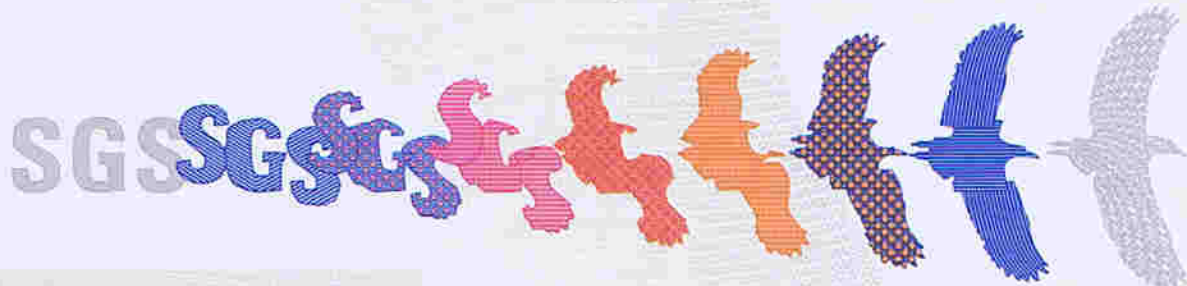


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The management system of

Hadleigh Health Technologies, LLC

30 Castro Avenue,
San Rafael, CA, 94901, 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

Bubble continuous positive airway pressure device (bCPAP), patient tubing, nasal prongs and connectors for paediatric use.

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 July 2018 until 12 May 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 03 March 2021
Issue 2. Certified since 12 May 2015

Certification is based on reports numbered WWW/MW 606721

Authorised by

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