

EC Certificate Full Quality Assurance System: Certificate US15/842155

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) 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 12 May 2015 until 12 May 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 3 March 2018
Issue 1. Certified since 12 May 2015

Certification is based on reports numbered WW/MW 606721

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

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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 13485:2003 EN ISO 13485:2012

For the following activities

**Design and development, manufacture, servicing, and distribution of
bubble continuous positive airway pressure device (bCPAP) for paediatric
use.**

This certificate is valid from 12 May 2015 until 12 May 2018
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 3 March 2018

Issue 1. Certified since 12 May 2015

Authorised by

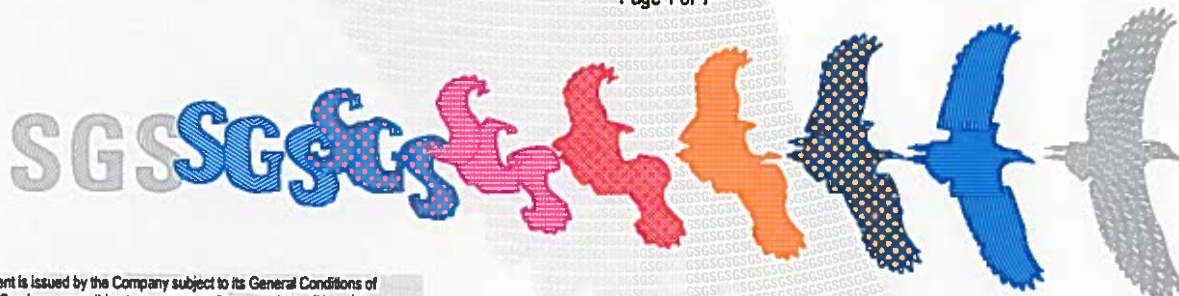
SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com



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