

# Certificate

acc. to **ISO 13485:2016**

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: **20-1607-Q**

TUV USA, Inc. hereby certifies that the quality management system of the company mentioned below is in conformance with **ISO 13485:2016** for Medical Devices-Quality Management Systems-Requirements for Regulatory Purposes.

**Hadleigh Health Technologies, LLC**  
**30 Castro Ave**  
**San Rafael, CA 94901, USA**

Additional sites covered by QM System: *N/A*

Scope:

**Design and Development, Manufacture, Servicing, and Distribution of Bubble Continuous Positive Airway Pressure Device (bCPAP), Patient Tubing, Nasal Prongs, and Connectors for Paediatric Use**

The validity of this certification document can be obtained by contacting the TUV USA, Inc. Office.

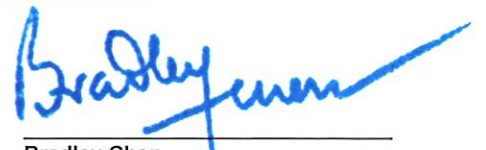
TUV USA, Inc. (a Member of the TÜV NORD Group)  
215 Main Street, Suite 1, Salem, NH 03079, USA  
Tel: 001-603-870-8023, Fax: 001-603-870-8026, Email: [medical-usa@tuv-nord.com](mailto:medical-usa@tuv-nord.com)



Audit Report Reference No.: **20-3843-SPA**  
Certificate Initial Issue Date: **22-APR-2020**  
Current Cycle Start Date: **13-MAY-2018**  
Certificate Revised Date: **01-MAY-2020**

Effective Date:  
**01-MAY-2020 / ed. 2**

Valid Until:  
**12-MAY-2021**



Bradley Chen  
Vice President, Americas  
Medical Products Division  
TUV USA, Inc.