

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)
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