

Certificate

acc. to **ISO 13485:2016**

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: 21-1602-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.

**Trinity Medical Devices, Inc.
135 Route 202/206
Bedminster, NJ 07921, USA**

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

Scope:

Design, Manufacturing, and Distribution of ECG electrodes and Reflective Probe Covers. Distribution of sterile laryngeal mask airways, sterile endotracheal tubes, sterile nasopharyngeal airways, non-sterile anesthesia breathing circuits and components, filters, heat and moisture exchangers with and without filters, manual resuscitators, ventilator tubing, aerosol delivery accessories, oxygen delivery accessories, blood pressure accessories, reflective temperature probe covers, and temperature probes

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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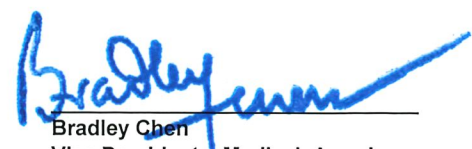
Audit Report Reference No.: 21-3981 RC

Initial Certification Date: 2019-11-01

Current Cycle Start Date: 2023-02-04

**Effective Date:
2023-02-04 / ed. 3**

**Valid Until:
2025-10-31**



Bradley Chen
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TUV USA, Inc.