

# Certificate

acc. to **ISO 13485:2016**

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: **21-1609-M**

TUV USA, Inc. hereby certifies that the quality management system of the company mentioned below is in conformance with ISO 13485:2016 under MDSAP for Medical Devices Requirements under the following jurisdictions:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure. **Canada:** Medical Devices Regulations – Part 1- SOR/98-282. **Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68. **USA:** United States: 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820.

**Atrion Medical Products, Inc.**  
**1426 Curt Francis Road NW, PO Box 564**  
**Arab, AL 35016, USA**

Facility ID: **F005727**

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

List of Products: **N/A**

**Scope:**

**Design, Development, and Manufacture of Sterile and Non-Sterile Inflation Devices, Syringes, and Needle Safety Products for the Medical Device Industry. Contract Manufacturing and OEM Manufacturing for the Medical Device Industry**

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**

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*TUV USA, Inc. is an MDSAP Recognised Auditing Organization*



Audit Report Reference No.: **21-3949 RC**

Certificate Initial Issue Date: **2021-08-20**

Current Cycle Start Date: **2022-03-30**

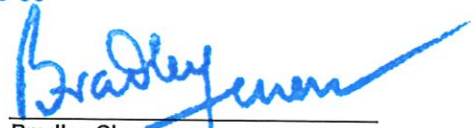
Certificate Revised Date: **2022-03-30**

Effective Date:

**2022-03-30 / ed. 2**

Valid Until:

**2025-03-30**



Bradley Chen  
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