Certificate

Management system as per

ISO 13485:2016 (MDSAP)

The Auditing Organization TUV USA, Inc. hereby confirms as a result of the audit, assessment, and certification decision according to ISO/IEC 17021-1:2015, that the organization

Atrion Medical Products, Inc.
1426 Curt Francis Road NW
Arab, Alabama 35016
United States of America
[Facility ID: F005727]

Operates a management system in accordance with the requirements of ISO 13485:2016 (MDSAP) and will be assessed for conformity within the 3-year term of validity of the certificate for 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, PMD Act (as applicable).
United States: 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820.

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 of Surgical irrigation tubing set, tubing sets, and contact lens cases for the Medical Device Industry

Certificate Registration No. 25-1608-M
Project No. 24-4120 RC

Issue Date:	2025-03-30
Reissue Date:	N/A
Expiry Date:	2028-03-29
Initial Certification Date:	2021-08-20

Salem, NH; 2025-03-25, Edition 1

Auditing Organization TUV USA, Inc.

The validity of this certificate may be obtained by contacting TUV USA at: +1 (603) 870-8023 (option 1) or via Email: medical-usa@tuv-nord.com

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MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

TUV USA, Inc. is recognized under the Medical Device Single Audit Program