C E R T I F I C A T E

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
PO Box 564
Arab, AL 35016, USA
[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. 21-1609-M
Audit Report No. 21-3949 SA2

Valid from 2024-04-16
Valid until 2025-03-29
Initial certification 2021-08-20

Recognized Auditing Organization
at TUV USA, Inc.

Salem, NH 2024-04-16, ed. 3

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

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

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