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
Tel: 001-603-870-8023, Fax: 001-603-870-8026, Email: medical-usa@tuv-nord.com
TUV USA, Inc. is an MDSAP Recognised Auditing Organization

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

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Bradley Chen
Vice President – Medical, Americas
Medical Products Division
TUV USA, Inc.