

# Certificate of Approval

This is to certify that the Management System of:  
**Atrion Medical Products Inc.**

1426 Curt Francis Road, Arab, AL, 35016, United States

MDSAP Facility Identifier: 04-757-1476

has been audited by Lloyd's Register Quality Assurance and found to conform to the following audit criteria:

**ISO 13485:2016 | EN ISO 13485:2016**

**Australia:**

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1  
(Excluding Part 1.6) – Full Quality Assurance Procedure

**Brazil:**

RDC ANVISA n. 16/2013

RDC ANVISA n. 23/2012

RDC ANVISA n. 67/2009

**Canada:**

Medical Devices Regulations – Part 1- SOR 98/282

**Japan:**

MHLW Ministerial Ordinance 169, Article 4 to Article 68  
PMD Act

**United States:**

21 CFR 803

21 CFR 806

21 CFR 807 – Subparts A to D

21 CFR 820



Cliff Muckleroy - Area Operations Manager Americas  
Issued by: Lloyd's Register Quality Assurance, Inc.

Certificate approval number: UQA00000242

Original approval:

Effective date: 2019 December 18

MDSAP/ISO 13485 – 2019 December 18

Expiry date: 2022 December 17

Certificate issue number: 10240560

The scope of approval is shown on the next page and bears the same certificate identity number

Approval number: MDSAP – 00022184



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To validate certificate authenticity visit: <http://www.lrqausa.com/help-and-support/Request-for-certificate-verification>

# Certificate of Approval

Certificate issue number: 10240560  
Approval number: MDSAP – 00022184

The scope of this approval is applicable to:

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.



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