

CERTIFICATEOF REGISTRATION

This is to certify that the management system of:

Parker Hannifin Corp. Precision Fluidics Division

(FIN F000918)

Main Site: 245 Township Line Road

Hatfield, Pennsylvania, 19440, United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

Canada: Medical Devices Regulations - Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

The management system is applicable to:

Design, manufacture, distribution, Installation and serving of Nitrous Oxide - Oxygen Conscious Sedation Flow Meters, Gas Scavenging Systems and Gas Distribution products for use by a physician, dentist or licensed healthcare professionals.

Certificate Number:

0093668-01

Initial Certification Date:

2019-08-12

Certification Effective Date:

2022-08-11

Certification Expiry Date:

2025-08-11





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