



# CERTIFICATE OF REGISTRATION

This is to certify that

## Trudell Medical International

725 Baransway Drive, London , Ontario N5V 5G4 Canada  
D-U-N-S: 20-329-8203

operates a

## Quality Management System

which complies with the requirements of

## ISO 13485:2016 and the requirements of the following regulatory authorities

**Australia:**

- Therapeutic Goods (Medical Devices) Regulations 2002: Schedule 3, Part 1 - Full Quality Assurance System

**Canada:**

- Medical Device Regulations SOR/98-282, Part 1

**Japan:**

- MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 128 (2014) Articles 4 to 68
- Japan PMD Act (as applicable)

**United States:**

- 21 CFR Part 803 - Medical Device Reporting
- 21 CFR Part 806 - Reports of Corrections and Removals
- 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing
- 21 CFR Part 820 - Quality System Regulation

for the following scope of certification

**The registration covers the Quality Management System for design, development, manufacture and distribution of aerosol drug delivery products, nebulizers and respiratory peak flow meters, dose indicators, incentive spirometer and active or non-active therapeutic devices.**

Certificate No.: CERT-0105702

Original Certification Date: 2019-02-27

File No.: 004649

Certification Effective Date: 2019-02-27

Issue Date: 2019-05-07

Certificate Expiry Date: 2022-02-26

Kevin Goodwin

General Manager Technical Services SAI Global Assurance



ISO 13485:2016

SAI Global is an MDSAP  
authorized auditing organization.



**Registered by:**

QMI-SAI Canada Limited (SAI Global), 20 Carlson Court, Suite 200, Toronto, Ontario M9W 7K6 Canada. This registration is subject to the SAI Global Terms and Conditions for Certification. While all due care and skill was exercised in carrying out this assessment, SAI Global accepts responsibility only for proven negligence. This certificate remains the property of SAI Global and must be returned to them upon request.  
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