# 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 repiratory peak flow meters, dose indicators, incentive spirometer and active or non-active therapeutic devices.**

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| 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

Certified System

**ISO 13485:2016**

SAI Global is an MDSAP authorized auditing organization.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM