

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## ClaroNav Kolahi Inc.

(FIN F007221)

Main Site: 1140 Sheppard Ave W, Unit 10

Toronto, Ontario M3K 2A2 Canada

has been registered by Intertek, an MDSAP recognised auditing organisation,  
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:** RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

**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 (as  
applicable)

### The management system is applicable to:

The design, development, manufacture, installation and servicing of  
surgical navigation products for use in the areas of ENT, cranial, and spine  
applications.

**Certificate Number:**

0074252-11

**Initial Certification Date:**

2018-04-13

**Date of Certification Decision:**

2024-04-03

**Certification Effective Date:**

2024-04-12

**Certification Expiry Date:**

2027-04-12



**intertek**

**Calin Moldovean**

President, Business Assurance

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