

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







Calin Moldovean President, Business Assurance

Intertek Testing Services NA, Inc. 4700 Broadmoor SE, Suite 200 Kentwood, MI, USA, 49512





In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request. Validity of this certificate may be verified at http://www.intertek.com/business-assurance/certificate-validation/ CT-MDSAP-2016-NA-EN-LT-P-3.JUN.21