

CERTIFICATEOF REGISTRATION

This is to certify that the management system of:

ClaroNav Kolahi Inc. (a subsidiary of ClaroNav Inc.)

(FIN F000777)

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: 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)

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:

0074252-09

Initial Certification Date:

2018-04-13

Date of Certification Decision:

2023-05-04

Certification Effective Date:

2023-05-04

Certification Expiry Date:

2024-04-12



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President, Business Assurance

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