

## **CERTIFICATE**OF REGISTRATION

This is to certify that the management system 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: 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)

## The management system is applicable to:

The design, development, manufacture, installation and servicing of surgical navigation and metrology products for use in the areas of Dentistry, ENT and Radiology.

**Certificate Number:** 

0074252-10

**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



MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

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