

## **CERTIFICATE**OF REGISTRATION

This is to certify that the management system of:

## X-Nav Technologies, LLC

(F00104)

Main Site: 1555 Bustard Road, Suite 75 & 110 Lansdale, Pennsylvania 19446 United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

**Australia**: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

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

## The management system is applicable to:

The design and development, manufacture and distribution, installation and service of Surgical Navigation Systems and Digital Radiography Systems for the areas of Dentistry and Otolaryngology (ENT).

Certificate Number:

0066555

**Revision Level: 06** 

**Initial Certification Date:** 

2017-08-31

**Certification Effective Date:** 

2023-08-30

**Certification Expiry Date:** 

2026-08-30



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President, Business Assurance

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