

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Air Techniques Inc.

(FIN F000728)

Main Site: 1295 Walt Whitman Road

Melville, New York, 11747, 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)

**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 OR 21 CFR 820.180 and 198, 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:

*Design, manufacture, installation and service of Digital Radiography Devices, Caries Detection Devices, Intraoral Cameras, Medical Grade Air Compressors, and Vacuum Pumps; Manufacture and service of X-Ray Equipment and PACS Software; Manufacture of Phosphor Storage Plates, Barrier Envelopes, and Camera Sheaths; and Caries Detection Devices; and distribution of Surface Disinfection Products. Contract manufacturing services of Digital Radiography Devices, Caries Detection Devices, Intraoral Cameras, X-Ray Equipment and PACS Software.*

**Certificate Number:**

0082944-01

**Initial Certification Date:**

2018-10-20

**Certification Effective Date:**

2020-12-23

**Certification Expiry Date:**

2021-10-19



**Intertek**

**Calin Moldovean**

President, Business Assurance

Intertek Testing Services NA, Inc.  
900 Chelmsford Street  
Lowell, MA, USA 01851

