

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 <u>OR</u> 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





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-30.apr.18