

*GMED certifies that the quality management system developed by*

**Air Techniques Inc**  
**1295 Walt Whitman Road**  
**Melville, New York 11747 UNITED STATES**

**Facility identifier (REPs-generated) : F000728**

*for the activities*

**Conception, fabrication, installation, distribution et prestations associées de dispositifs de radiographie numérique, de compresseurs d'air à usage médical, de pompes à vide, Equipment à Rayons X et processeurs de film radiographique. (voir la portée complète dans l'addenda)**

*Design, Manufacture, Installation, distribution and service of Digital Radiography Devices, Medical Grade Air Compressors, Vacuum Pumps, X-ray Equipment and Radiographic Film Processors. (see full scope in the addendum)*

*performed on the location(s) of*

**Air Techniques, Inc. 1295 Walt Whitman Road Melville, New York 11747 USA**

**has been audited and found to conform to the requirements of the international standard ISO 13485 : 2016 and following regulatory requirements**

Australia	Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
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
Japan	MHLW MO 169 PMD Act
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807 - -Subparts A to D 21 CFR 821 (where applicable)

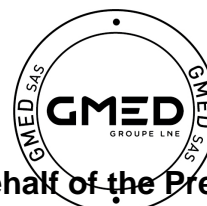
**Début de validité / Effective date December 19th, 2023 (included)**

**Valable jusqu'au / Expiry date : October 19th, 2024 (included)**

**Etabli le / Issued on : December 19th, 2023**



GMED is authorised under the Medical Devices Single Audit Program  
 This certificate is issued according to the rules of GMED Certification  
 The validity of this certificate can be verified on [www.gmed.fr](http://www.gmed.fr)



DocuSigned by:  
*Béatrice LYS*  
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**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**

**Ce certificat couvre les activités suivantes (description détaillée complète) :**

*This certificate covers the following activities (full detailed description):*

**Conception, fabrication, installation, distribution et prestations associées de dispositifs de radiographie numérique, de compresseurs d'air à usage médical, de pompes à vide, Equipment à Rayons X et processeurs de film radiographique.**

**Fabrication et distribution de plaques au phosphore, d'enveloppes de barrière, de produits de désinfection de surfaces, de dispositifs de détection de caries, de caméras intra-orales, de logiciel d'archivage d'images et de communication (PACS) et de masques de sédation.**

*Design, Manufacture, Installation, distribution and service of Digital Radiography Devices, Medical Grade Air Compressors, Vacuum Pumps, X-ray Equipment and Radiographic Film Processors.*

*Manufacture and distribution of Phosphor Storage Plates, Barrier Envelopes, Surface Disinfection Products, Caries Detection Devices, Intraoral Cameras, PACS Software and Scavenging Masks.*

**Ce certificat couvre les activités et les sites suivants :**

*This certificate covers the following activities and sites:*

**Air Techniques, Inc.**  
1295 Walt Whitman Road  
Melville, New York 11747  
United States

**Conception, fabrication, installation, distribution et prestations associées**

Design, Manufacture, Installation, distribution and service

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**1 site / 1 site**



DocuSigned by:  
*Béatrice LYS*  
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**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**