intertek
Total Quality. Assured.

EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Air Techniques Inc.

Main Site: 1295 Walt Whitman Road, Melville, New York 11747, United States

Product Category:

- Non-active devices to record X-Ray diagnostic images.

For further identification of the products covered, see the MDD product list/product schedule.

*Previously certified by Intertek AMTAC (NB0473) to date 25 January 2018

Certificate Number:
41371408-02

Initial Certification Date:
25 January 2018*

Certificate Valid from:
25 January 2019

Certificate Expiry Date:
24 January 2024

SWEDAC ACKREDITERING
Ackred. nr 1003
ISO/IEC 17021

Peter Nermander
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

21 January 2019
Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

intertek
Total Quality. Assured.

MDD – Product List

Products included in the certificate no: 41371408-02
Issued to: **Air Techniques Inc.**
1295 Walt Whitman Road
Melville, New York 11747
United States

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Non-active devices to record X-Ray diagnostic images					
	Phosphor Storage Plates, 73445-0	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73445-1	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73445-2	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73445-3	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73445-4	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73445-20	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73445-2B	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73578-5	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73578-57	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73578-6	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73578-7	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73578-8	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73578-9	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73578-8M	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73578-10M	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73578-14M	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73445J-0	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73445J-1	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73445J-2	IIa	No	45256	Jan 25, 2018

Intertek Semko AB
Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00 , Fax +46 8 750 60 30, www.sweden.intertek-etlsemko.com
Registered in Sweden: No SE556024059901, Registered office: As address

intertek
Total Quality. Assured.

MDD – Product List

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	Phosphor Storage Plates, 73445J-3	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, 73445J-4	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, F3461-0	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, F3461-1	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, F3461-2	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, F3461-3	IIa	No	45256	Jan 25, 2018
	Phosphor Storage Plates, F3461-4	IIa	No	45256	Jan 25, 2018

Sign date: 21 January 2019
Valid date: 25 January 2019

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

Intertek Semko AB is a Notified Body according to the Directive 93/42/EEC on medical devices, with identification number 0413.

Intertek Semko AB
Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00 , Fax +46 8 750 60 30, www.sweden.intertek-etlsemko.com
Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Decision Report

Certificate No: 41371408-02
Date: 21 January 2019
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

Air Techniques Inc.
Attn: Vincent Vega
1295 Walt Whitman Road
Melville, New York 11747
United States

Purpose	Assement to reinstate and renew the currently suspended EC Certifcate #41371408-01 according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II. The EC Certificate #41371408-01 was suspended 31 October 2018 due to major findings for current ongoing conformity assessment and audit activities
Activity	Certification audit was performed 03 July 2018 in Shenzhen by Juan Zamora and Orpha James. Special visit audit was performed 08 October 2018 to close major finding. The technical files was reviewed by Lian Zhang at Intertek's office.
Scope of assessment	Nebulizers, Suction devices and Oxygen concentrators, Class IIa
Result	No major non conformities are now open and presented corrective action plans for minor non conformities have been examined and approved by us. The terms to reinstate the EC Certificate are now fulfilled and the EC Certificate #41371408-01 can be reinstated and renewed for a new five year period.
Certificate Valid from	25 January 2019
Conclusions/Decisions	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II will be issued. The Certificate is valid for products specified in the "MDD – Product List".
Follow-up assessments	Follow-up assessments are going to be performed once a year.

Appeals

Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Others

Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD