



**Awareness Technology, Inc.**



## Declaration of Conformity

Product name :	<b>Product identification</b>
Model/Type :	Stat-Fax®, Chemistry Analyzer P1904
Name :	<b>Manufacturer</b>
Address :	Awareness Technology, Inc. 1935 S.W. Martin Hwy. Palm City, Florida 34990
Country :	USA
Representative:	<b>Authorized Representative in Europe</b>
Name :	Emergo Europe
Address :	Prinsessegracht 20 2514 AP The Hague
Country :	The Netherlands
tel:	+31 70 345 8570
fax:	+31 70 346 7299


## Means of Conformity

*Awareness Technology, Inc. declares that the product listed is in conformity with the Annex III, essential requirements and provisions of Council Directive:*

*98/79/EC*

*And is in conformance with the following standards:*

*EN 61326-1 / EN 55022  
EN 61010-1*

Place and Date:	<b>Signature</b> Awareness Technology, Inc.
Signature :	
Name :	Steve Andrus Quality Manager

December 01, 2003  
Revised May 7<sup>th</sup>, 2018

Analizator biochimic cu cuva , semiautomat, cu sistem de tip deschis			
Descriere	Analizator semiautomat destinat analizelor biochimice cu sistem de tip deschis de reactivi		Specificatii tehnice Stat Fax Stat Fax 1904+Mosquito
Parametrul		Specificația	
Tip sistem		Sistem deschis de reactivi	Sistem deschis de reactivi
Tip probă	Ser	da	Da
	Plasmă	da	Da
	Urina	da	da
Reagenți	Lichid	da	Da
	Cu posibilitatea de a fi substituiți	da	Da
Incubator	Temperatura termostatare	37°C	37°C
	Capacitatea	minim 8 tuburi	12 tuburi
Cuva absorbanta	cuva	da	Da (Mosquito)
	tip	reutilizabila	reutilizabila
	Volum reactiv/investigatie	≤500 mcl	≤500 mcl
	Temperatura termostatare	37°C	37°C
Regimuri de masurare	Punct final	da	da
	Cinetic	da	da
	Multipoint cinetic	da	da
Sursa de lumină		Minim 6 lungimi de undă	6 lungimi de unda - 340, 405, 450, 505, 545, 600nm
Data management	Display	da	Da, LCD
	Memorie internă	da	da
	Imprimantă integrată	da	Da, termica
Calibrarea	automată	da	Da
Alimentarea	Rețeaua electrică 220 V, 50 Hz	da	220 V, 50 Hz
	Cuva absorbanta tip	Reutilizabila, 2 buc	Reutilizabila, 2 buc
Accesorii	Bec	≥3 buc	3 buc
Consumabile	Eprubete (cuve) pentru incubarea reactivelor compatibile cu incubatorul analizatorului	≥1000 buc	Eprubeta pentru Stat Fax 1000 buc

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Awareness Technology, Inc.

Main Site: 1935 SW Martin Highway

Palm City, Florida 34990 USA

Additional site: 2325 SW Martin Highway, Palm City, Florida 34990 USA

has been assessed by Intertek as conforming to the requirements of:

## ISO 13485:2016

The quality management system is applicable to:

The design, development, manufacture, distribution, installation and service of IVDD General Laboratory Instruments.

Additional site: Manufacturing, Quality Control, Distribution, Shipping, Installation and Service.

**Certificate Number:**

9362-8

**Initial Certification Date:**

March 28, 2012

**Date of Certification Decision:**

March 24, 2021

**Issuing Date:**

March 27, 2021

**Valid Until:**

March 27, 2024



**Intertek**



A handwritten signature in black ink, appearing to read "Calin Moldovean".

**Calin Moldovean**  
President

Intertek Testing Services NA Ltd.,  
1829, 32nd avenue, Lachine, QC, H8T 3J1,  
Canada





**Awareness Technology, Inc.**



**Intertek**

**Declaration of Conformity**

**Product Identification**

Product name	Model/Type
Microstrip Reader	Stat Fax 300 series
	Stat Fax 4700 series
Chemistry Analyzer	Stat Fax1900 series
	ChemWell 2900 series
	Stat Fax 3300 series
	Stat Fax 4500 series
	ChemWell-T 4600 series
	ChemWell Fusion 4800 series
ELISA Analyzer	ChemWell2 5100 series
Automated Analyzer	ChemWell-RPR 5800 series
Microplate Reader	Stat Fax 2100 series
	Stat Fax 3200 series
	Stat Fax 4200 series
Incubator / Shaker	Stat Fax 2200 series
Microplate Washer	Stat Fax 2600 series
Electrolyte Analyzer	ISE 3900 series
Luminometer	LumiStat 4100 series
	LuMate 4400 series
	LumiStat 4900 series
Microplate Reader	ChroMate 4300 series

**Manufacturer**

Name : Awareness Technology, Inc.  
Address : 1935 SW Martin Hwy  
Palm City, Florida 34991  
Country : USA

**Means of Conformity**

*Awareness Technology, Inc. declares that the product listed is in conformity with the Annex III, essential requirements and provisions of Council Directive: 98/79/EC and is in conformance with the following standards: EN 61326-1 EMC / EN 61010-1 Safety*

**Representative: Authorized Representative in Europe**

Name : Emergo Europe  
Address : Prinsessegracht 20  
2514 AP The Hague  
Country : The Netherlands  
Telephone : +31 70 345 8570  
Fax Number : +31 70 346 7299

*Self-certified under the principles of ISO 13485:2016  
Registered Medical Device Quality System under ISO 13485:2016*

Place and date:

**Awareness Technology, Inc.**

**October 26, 2016**

**Revised May 7 2018**

Signature:

Name:

Steve Andrus

Title:

Quality Manager