

# 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.

Main site: Management, QA, Design, Sales, Service

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

**Certificate Number:**

9362

**Revision Level:** 09

**Initial Certification Date:**

March 28, 2012

**Date of Certification Decision:**

December 19, 2023

**Issuing Date:**

December 19, 2023

**Valid Until:**

December 18, 2026



**intertek**

The SCC Accreditation Symbol is an official symbol of the Standards Council of Canada, used under license.

**Calin Moldoveanu**  
President

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





# Awareness Technology, Inc.

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## Declaration of Conformity

**Product identification**  
Product name : Microplate Washer  
Model/Type : P2600 Series

**Manufacturer**  
Name : Awareness Technology, Inc.  
Address : PO Drawer 1679  
Palm City, Florida  
Country : USA

**Authorized Representative in Europe**  
Representative:  
Name : Emergo Europe  
Address : Molenstraat 15  
2513 BH 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:*

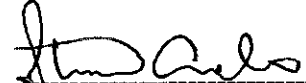
98/79/EC

*And is in conformance with the following standards:*

EN 61326-1 / EN 55022  
EN 61010-1

Place and Date: **Signature**  
Awareness Technology, Inc.

December 01, 2003

Signature : 

Name : Steve Andrus  
Quality Manager

  
Chris Mauer  
Compliance Engineer



Awareness Technology, Inc.



## Declaration of Conformity

|                 |                                     |
|-----------------|-------------------------------------|
| Product name :  | Product Identification              |
| Model/Type :    | Microplate Washer                   |
|                 | P2600 Series                        |
|                 | Manufacturer                        |
| Name :          | Awareness Technology, Inc.          |
| Address :       | PO Drawer 1679                      |
|                 | Palm City, Florida                  |
| Country :       | USA                                 |
| Representative: | Authorized Representative in Europe |
| Name :          | Emergo Europe                       |
| Address :       | Molenstraat 15                      |
|                 | 2513 BH The Hague                   |
| Country :       | The Netherlands                     |
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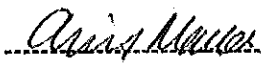
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|                 |                                                                                      |                                                                                       |
|-----------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Place and Date: | Signature                                                                            |                                                                                       |
|                 | Awareness Technology, Inc.                                                           | December 01, 2003                                                                     |
| Signature :     |  |  |
| Name :          | Steve Andrus                                                                         | Chris Mauer                                                                           |
|                 | Quality Manager                                                                      | Compliance Engineer                                                                   |



# Stat Fax<sup>®</sup> 2600 - Microplate Washer

## Features

Washes flat, round, and v-bottom plates and strips.

No user adjustments required, automatic calibration, alignment, and last row detection.

Large, non-volatile memory for up to 50 user-entered wash protocols; Six factory-programmed wash/rinse modes.

Programmable automatic rinse cycle.

Precision operation with constant monitoring of vacuum and pressure. For extra quiet operation, internal pump cycles on only when needed.

Ready to run; 3 bottles, aerosol shield, and 8-probe manifold included.

## Options & Accessories

12-probe and 16-probe manifolds.

Extra wash, rinse, and waste bottles.

**2600 Plus added features:**  
**Dual wash bottle system for added versatility and convenience.**  
**Individual row selection for partial plate washing.**  
**Built-in plate mixing function.**

**Distributed by:**



Awareness Technology, Inc. PO Drawer 1679, Palm City, FL 34991 (772) 283 6540, fax (772) 283 8020  
 web site: <http://www.awaretech.com>, email: [info@awaretech.com](mailto:info@awaretech.com)

*Cost Effective by Design<sup>®</sup>*

# Stat Fax<sup>®</sup> 2600

## Microplate Washer Specifications

### ***Fluid Performance (with 8-probe head)***

Residual Volume: <3µl.  
Dispense accuracy: <3% CV at 300µl.  
Processing time (full plate): 55 seconds aspirate/dispense with single or double aspirate.  
Liquid Contact Materials: Stainless steel, Delrin, silicone, nylon, PVC, polypropylene, HDPE.

### ***Electronic***

Display: Two-line LCD, alphanumeric, 24 characters per line.  
Keyboard: 16-key, domed membrane switch, 4x4, enunciating.  
Power Requirements: 115V or 230V AC, 50-60Hz (switch selectable).  
Microprocessor: Z80A or Z180.  
Non-volatile Memory: Battery supported RAM, holds approx. 50 wash protocols.

### ***Software***

Washing Programs: Aspirate, dispense, mix, soak - up to 99 minutes 99 secs.  
Special Menu Options: *Auto alignment* - senses physical geometry of the head, plate, and carrier mechanism.  
*Standby* - disables pumps and releases vacuum and pressure.  
*Self Check* - performs internal performance tests and auto alignment.  
*Auxiliary* - selection of well type, select auto/manual well depth and dispense depth, constant plate cycle time, viewing of pre-programmed tests, configure auto-rinse, set the time and date.

### ***Other***

Bottles: Wash and waste 2L, rinse 1L, plastic with volume sensor probes.  
Enclosure: Fire retardant ABS plastic cover with metal base.  
Dimensions: Approx. 15.5 x 13.5 x 7.5in (39 x 34 x 19cm). Weight 19 lbs. (8.6kgs).  
Certifications: NRTL Listed, CE Mark.



### ***2600 Plus model - added features***

Bottles: Wash-1, Wash-2, and Waste (2L), Rinse (1L), plastic with volume sensor probes.  
Mix function: Programmable mix time during soak cycle.  
Row selection: User may select individual rows to wash, skipping used wells.



## DICHIARAZIONE DI CONFORMITÀ CE EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE "Dispositivi Medico-Diagnostici In Vitro" e s.m.i.  
according to Annex III of the Directive 98/79/EC on "In Vitro Diagnostic Medical Devices" as amended

fabbricante **VACUTEST KIMA S.r.l. - articoli per laboratori analisi**  
manufacturer **disposable labware**

indirizzo **Via dell'Industria, 12**  
address **35020 Arzergrande (PD) - Italia**

telefono **+39-049-9720624**  
phone

fax **+39-049-9720182**  
fax

posta elettronica **info@vacutestkima.it**  
e-mail

identificazione dei prodotti  
product identification

**Sistema di prelievo di sangue e altri liquidi biologici  
mediante provette con vuoto predeterminato in plastica  
"VACUTEST KIMA".**

**"VACUTEST KIMA" vacuum blood and biological liquids  
collection tubes in plastic.**

nome commerciale  
brand name

**"VACUTEST KIMA"**

classificazione dei prodotti  
product classification

**dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.  
devices other than those mentioned in Annex II of the Directive 98/79/EC as amended**

### Si dichiara

sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. "Dispositivi Medico-Diagnostici In Vitro".

Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

### Hereby we declare

under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on "In Vitro Diagnostic Medical Devices".

All the supporting documents, as required by Annex III, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data  
place and date

**Arzergrande, 01/01/2015**

firma  
signature

**Assicuratore Qualità / Quality Manager  
Giovanni Chiarin**



## Stat Fax 2600



*Spălător automat de microplăci ELISA*

**Producător:** Awareness Technology Inc. SUA

**Stat Fax 2600** este un spălător pentru microplăci sau stripuri cu fundul plat, rotund sau în formă de V. Se calibrează și se poziționează automat, detectând ultimul rând, fără intervenția Operatorului.

Timpul maxim programabil pentru aspirare, dozare sau uscare este de 99 min și 99 sec.

**Mod de operare:** monitorizarea permanentă a vacuumului și presiunii, cu pornirea ciclului de pompare numai în caz de necesitate, pentru silențiozitate în operare.

Se pot programa cicluri automate de spălare.

**Volum rezidual:** < 3 m l

**Precizia dozării:** Coef. de variație <3 % la 200 m l

**Viteza de lucru:** 1 ciclu de spălare a unei plăci cu dublă aspirare durează 100 sec., cu aspirare simplă durata se reduce la 67 sec.

**Afisaj:** cu cristale lichide, alfanumeric, cu 24 de caractere pe 2 rânduri.

**Tastatură:** 16 taste cu membrană, cu confirmare sonoră.

**Memorie:** permanentă, cu posibilitatea de memorare până la 50 de protocoale de spălare definite de utilizator.

Aparatul se livrează cu toate anexele necesare incluse: 3 flacoane de câte 1L pentru lichidele de spălare, clătire și reziduale, capac de protecție, element de spălare cu 8 duze.