

# 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



SCC Accredited  
CB-MS



OCSM  
Accredited CCN

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

**intertek**

**Calin Moldoveanu**  
President

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





## Awareness Technology, Inc.

### Declaration of Conformity

#### Product identification

Product name : Stat Fax, Microstrip Reader  
Model/Type : P303 Plus Series  
EDMS Code : 20.10.01.01.00  
Class : Other IVD Devices – Self-declared

#### Manufacturer

Name : Awareness Technology, Inc.  
Address : P.O. Box 1679  
Palm City, Florida 34991  
Country : USA

#### Authorized Representative in Europe

Representative:  
Name : Emergo Europe  
Address : Molenstraat 15  
2513 BH The Hague  
Country : The Netherlands  
Telephone : +31 70 345 8570  
Fax Number : +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 EMC / EN 61010-1 Safety*

#### Signature

Place and Date: Awareness Technology, Inc.

February 4, 2009

Signature :

Name :  
Title :

Steve Andrus  
Quality Manager

Chris Mauer  
Compliance Engineer



## Awareness Technology, Inc.

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### Declaration of Conformity

#### Product identification

Product name : Stat Fax® Microstrip Reader  
Model/Type : 4700 Series  
EDMS Code : 21 01 10 01  
Class : Other IVD Devices – Self-declared

#### Manufacturer

Name : Awareness Technology, Inc.  
Address : P.O. Box 1679  
Palm City, Florida 34991  
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:*

*IEC 61326-1 / IEC 61326-2-6  
EN 61010-1 / EN 61010-2-101*

#### Signature

Place and Date: Awareness Technology, Inc.

December 12, 2012

Signature :

Name :

Steve Andrus  
Quality Manager

Doug Shields  
Compliance Engineer