

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.

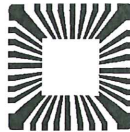
February 4, 2009

Signature :

Name :
Title :

Steve Andrus
Quality Manager

Chris Mauer
Compliance Engineer



Awareness Technology, Inc.

Declaration of Conformity

Product identification

Product name : Stat Fax® Chemistry Analyzer
Model/Type : P3300 Series
EDMS Code : 20.10.01.01.00
Class : Other IVD Devices – Self-declared

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
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.

October 15, 2009

Signature :

Name :

Steve Andrus
Quality Manager

Chris Mauer
Compliance Engineer



Awareness Technology, Inc.

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