

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

intertek

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

Calin Moldovean
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 :

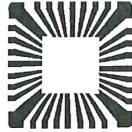
Steve Andrus

Chris Mauer

Title :

Quality Manager

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
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Place and Date:	Signature Awareness Technology, Inc.	October 15, 2009
Signature :		
Name :	Steve Andrus Quality Manager	Chris Mauer Compliance Engineer