

# **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





Calin Moldovean President

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





In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.



### **Declaration of Conformity**

#### **Product Identification**

Product name	Model/Type
Microstrip Boodor	Stat Fax 300 series
Microstrip Reader	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
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 Address		Awareness Technology, Inc. 1935 SW Martin Hwy
Country		Palm City, Florida 34991 USA
Country	Ċ	00/1
Representative: Authorized Representative		
in Europe		
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

Self-certified under the principles of ISO 13485:2003 Registered Medical Device Quality System under ISO 13485:2003

Place and date:

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Signature: Name: Title: Awareness Technology, Inc.

October 26, 2016

Steve Andrus

Steve Andrus Quality Manager