intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

Medica Corporation

Main Site: 5 Oak Park Drive

Bedford, Massachusetts 01730 United States

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, Service, Distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, in-vitro diagnostic analyzers/software used in the diagnosis and management of cancer, immune status, disease status, autoimmune status, cardiac markers, protein metabolism, endocrine disorders, blood analytes, urinalysis, blood gases.

Certificate Number:
0082581-01

Initial Certification Date:
2009-04-17

Certificate Issue Date:
2019-01-01

Certificate Expiry Date:
2021-04-16

SCC Accredited CB-MS
OCSM Accrédité CCN

Calin Moldovean
President

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

CE

Awareness Technology, Inc.

INTERTEK ISO 13485:2003

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	:	Steve Andrus	Chris Mauer
Name	:	Steve Andrus	Chris Mauer
Title	:	Quality Manager	Compliance Engineer

CE

Awareness Technology, Inc.

ISO 13485:2003

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

BUREAU VERITAS
Certification

Certificate

Awarded to

Avantor Performance Materials Poland S.A.

ul. Sowińskiego 11, 44-101 GLIWICE
POLAND

Bureau Veritas Certification certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

STANDARD

ISO 9001:2015

SCOPE OF SUPPLY

SALES OF CHEMICAL SERVICES AND CHEMICAL PRODUCTS INCLUDING FINE CHEMICALS, ENNOBLED CHEMICALS, HIGH PURITY SOLVENTS, CHEMICAL SERVICES.

PRODUCTION AND TESTING OF CHEMICAL PRODUCTS INCLUDING FINE CHEMICALS, ENNOBLED CHEMICALS AND HIGH PURITY SOLVENTS.

Certification Cycle Start Date: **15 September 2018**

Subject to the continued satisfactory operation of the organisation's Management System, this certificate is valid until: **14 September 2021**

To check this certificate validity please call: +48 22 549 04 00
Further clarification regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.

Issue Date: 29 June 2018

Certificate Number: **PL008875/P**

Piotr Popławski
Local Technical Manager

PCA
Polskie Centrum Akredytacji
Certyfikacja Systemów Zarządzania
AC 081
QMS

MIX
Paper from responsible sources
FSC® C074440

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 02 16316 019

Manufacturer:

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen
GERMANY

Facility(ies):

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10, 72810 Gomaringen, GERMANY

Product Category(ies):

Elecrosurgical Unit and accessories
Argon Coagulation Unit and accessories
Electrode handles
Active electrodes and instruments
monopolar and bipolar forceps
endoscopic and laparoscopic instruments
instruments for vessel sealing
neutral electrodes
bipolar scissors

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713102471

Valid from: 2017-03-09
Valid until: 2022-03-08

Date, 2017-03-08

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

A1 / 04.11

Zertifiziervertrag

Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.

Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:

– Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:

– Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.

– Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract

Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.

On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuev-sued.de/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:

– Validity of the quoted test standard(s)

In addition for certificates with the right to use a certification mark and for QM certificates:

– Conditions for an adequate manufacturing are maintained

– Regular surveillance of the facility is performed

Akkreditierungen / Benennungen (Status 14.10.2013) /
Accreditations / notifications (as of 2013-10-14)

Deutschland / Germany

Produktsicherheitsgesetz (ProdSG) /
Product Safety Act (ProdSG)

Europa / Europe

- Niederspannungsrichtlinie 2006/95/EG
- Spielzeugrichtlinie 2009/48/EG
- Richtlinie für aktive medizinische Implantate 90/385/EWG
- Richtlinie für Medizinprodukte 93/42/EWG
- Richtlinie für In-vitro-Diagnostika 98/79/EG
- Richtlinie für Gasverbrauchseinrichtungen 2009/142/EG
- Richtlinie für persönliche Schutzausrüstungen 89/686/EWG
- EMV-Richtlinie 2004/108/EG
- Richtlinie für Sportboote 94/25/EG + 2003/44/EG
- Richtlinie für Maschinen 2006/42/EG
- Richtlinie für Ex-Schutz Geräte 94/9/EG

- Low Voltage Directive 2006/95/EC
- Toys Directive 2009/48/EC
- Directive for Active Implantable Medical Devices 90/385/EEC
- Directive for Medical Devices 93/42/EEC
- Directive on In Vitro Diagnostic Medical Devices 98/79/EC
- Directive for Gas Appliances 2009/142/EC
- Directive for Personal Protective Equipment 89/686/EEC
- EMC Directive 2004/108/EC
- Directive for Recreational Craft 94/25/EC + 2003/44/EC
- Directive for Machinery 2006/42/EC
- Directive for Ex Safe Equipment 94/9/EC

- ENEC Agreement for luminaires, household and IT equipment

USA

- Nationally Recognized Testing Laboratory (NRTL) to 29 CFR 1910.7 by OSHA
- Accredited for FDA 510(k) Third Party Review
- Conformity Assessment Body to the MRA for Medical Devices; FDA QSReg Inspections, FDA 510(k) Third Party Review

Asien-Pazifik Region / Asia Pacific

- Recognized Certification Body to Electrical Products (Safety) Regulation; Hong Kong
- Konformitätsbewertungsstelle / Conformity Assessment Body to the MRA for Medical Devices; Australien / Australia
- Konformitätsbewertungsstelle / Conformity Assessment Body to the MRA for Medical Devices; Neuseeland / New Zealand

Weltweit / Worldwide

- NCB im CB-Scheme des IECEE /
  NCB in the CB Scheme of IECEE
- ExCB im IECEx-Scheme des IECEE /
  ExCB in the IECEx Scheme of IECEE
- Zertifizierstellen durch DAkkS akkreditiert
  DE-ZE-11321-01, DE-ZM-11321-09 und DE-ZM-11321-01.
  Certification Bodies accredited by DAkkS
  DE-ZE-11321-01, DE-ZM-11321-09 and DE-ZM-11321-01.

Zertifizierstelle für Produkte / Certification Body for Products • e-mail ps-zert@tuev-sued.de
Zertifizierstelle für Medizinprodukte / Certification Body for Medical Devices • e-mail medical_devices@tuev-sued.de
Kundenservice / Clients Services • Phone +49/89/50 08-42 61 • Fax +49/89/50 08-42 30 • e-mail ps-zert@tuev-sued.de

Medica Corporation
5 Oak Park Drive
Bedford, Massachusetts 01730
Tel 781 275 4892
Fax 781 275 2731
www.medicacorp.com

Declaration of Conformity CE

Product Name:	**Model/Type:**
EasyStat and accessories per attachment	pH/pCO2/pO2/Na/K/Ca/Hct, pH/pCO2/pO2/Na/K/Cl/Hct
EasyBloodGas and accessories per attachment	pH/pCO2/pO2

Manufacturer

Medica Corporation
5 Oak Park Drive, Bedford, Massachusetts, 01730, USA

Representative

EC REP Emergo Europe, Prinsessegracht 20,
2514 AP The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

Means of Conformity

Medica Corporation declares that the products listed are covered by Annex III of Directive 98/79/EC. These products are self-certified since they are for professional use only and are not listed on Annex II, List A or Annex II, List B of Directive 98/79/EC. In addition, they are in conformity with the Annex I, "Essential Requirements" and provisions of council Directive 98/79/EC for In Vitro Diagnostic Medical Devices, Directive 2011/65/EU Restriction of Hazardous Substance in Electrical and Electronic Equipment, and the corresponding national laws of the Member States.

Place and Date: Bedford, Massachusetts, USA, September 27, 2018

Signature:

Name: Photios Makris, Ph.D.
Title: VP, Regulatory Affairs

EasyBloodGas and EasyStat Accessories

Catalog No.	Accessory	EDMA Code
6001	EasyBloodGas Analyzer	21 07 11 01
7001	EasyStat Analyzer	21 07 11 03
7017	EasyStat Analyzer	21 07 11 03
6201	EasyStat/EasyBloodGas pH Electrode	11 70 31 04
6202	EasyStat/EasyBloodGas pCO2 Electrode	11 70 31 04
6203	EasyStat/EasyBloodGas pO2 Electrode	11 70 31 04
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode	11 04 04 01
6101	EasyBloodGas Reagent Module	11 70 31 50
6301	EasyBloodGas Troubleshooting Kit	21 04 10 01
6303	EasyQC Level 1 Blood Gas and Electrolyte Quality Control	11 70 31 50
6304	EasyQC Level 2 Blood Gas and Electrolyte Quality Control	11 70 31 50
6305	EasyQC Level 3 Blood Gas and Electrolyte Quality Control	11 70 31 50
2118	Daily Cleaning Solution	11 01 01 27
6402	Red Test Dye Solution	11 30 01 11
6503	EasyBloodGas Capillary Tube Kit	21 07 11 01
6603	EasyBloodGas Demonstration Kit	21 07 11 01
6306	EasyBloodGas Sampler	21 07 11 01
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 07 11 03
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper	21 07 11 03
6506	EasyBloodGas Sensor Module	21 07 11 01
6507	EasyBloodGas Valve Module	21 07 11 03
6508	Compression Plate	21 07 11 03
6537	Serial Cable, 9-pin	21 07 11 03
6520	Barcode Reader Kit	21 07 11 03
7101	EasyStat Reagent Module	11 70 31 10
7205	EasyElectrolyte/EasyStat Na Electrode	11 04 01 07
7206	EasyElectrolyte/EasyStat K Electrode	11 04 01 06
7207	EasyStat Ca Electrode	11 04 01 02
7208	EasyStat Cl Electrode	11 04 01 03
7301	EasyStat Troubleshooting Kit	21 07 11 03
7309	Bi-Level Hematocrit Quality Control	11 50 02 90
7603	EasyStat Demonstration Kit	21 07 11 03
7303	EasyBloodGas/EasyStat Capillary Tube Kit	21 07 11 03
7306	EasyStat Sampler	21 07 11 03
7304	EasyStat Pump Tube	21 07 11 03
7506	EasyStat Sensor Module	21 07 11 03
7302	Probe Wipers	21 07 11 03

Medica Corporation
5 Oak Park Drive
Bedford, Massachusetts 01730
Tel 781 275 4892
Fax 781 275 2731
www.medicacorp.com

Declaration of Conformity CE

Product Name:	Model/Type:
EasyLyte and accessories per attachment	EasyLyte Na/K, Na/K/Cl, Na/K/Li, Na/K/Cl/Li, Na/K/Ca/pH, Na/K/Cl/Ca/Li
EasyElectrolytes and accessories per attachment	EasyElectrolytes Na/K/Cl, Na/K/Li

Manufacturer

Medica Corporation
5 Oak Park Drive, Bedford, Massachusetts, 01730, USA

Representative

EC REP Emergo Europe, Prinsessegracht 20,
2514 AP The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

Means of Conformity

Medica Corporation declares that the products listed are covered by Annex III of Directive 98/79/EC. These products are self-certified since they are for professional use only and are not listed on Annex II, List A or Annex II, List B of Directive 98/79/EC. In addition, they are in conformity with the Annex I, "Essential Requirements" and provisions of council Directive 98/79/EC for In Vitro Diagnostic Medical Devices, Directive 2011/65/EU Restriction of Hazardous Substance in Electrical and Electronic Equipment, and the corresponding national laws of the Member States.

Place and Date: Bedford, Massachusetts, USA, September 27, 2018

Signature:

Name: Photios Makris, Ph.D.
Title: VP, Regulatory Affairs

EasyLyte Accessories

Catalog No.	Accessory	EDMA Code
2004	EasyLyte Na/K Analyzer	21 07 11 02
2014	EasyLyte Plus Na/K/Cl Analyzer	21 07 11 02
2015	EasyLyte Lithium Na/K/Li Analyzer	21 07 11 02
2016	EasyLyte Calcium Na/K/Ca/pH Analyzer	21 07 11 02
2021	EasyLyte Na/K/Cl/Li Analyzer	21 07 11 02
2030	EasyLyte EXPAND Analyzer, Na/K/Cl/Ca-Li	21 07 11 02
2070	EasyLyte EasySampler	21 07 11 02
2101	EasyLyte K+ Electrode	11 04 01 06
2102	EasyLyte Na+ Electrode	11 04 01 07
2113	EasyLyte Cl- Electrode	11 04 01 03
2106	EasyLyte Li+ Electrode	11 04 01 04
2150	EasyLyte Ca++ Electrode	11 04 01 02
2151	EasyLyte pH Electrode	11 70 31 02
2152	EasyLyte Disposable Reference Electrode	11 04 04 01
2103	EasyLyte Reference Electrode	11 04 04 01
2258	EasyLyte Membrane Assembly	21 07 11 02
2120	EasyLyte Na/K 800 ml Solutions Pack	11 04 04 02
2121	EasyLyte Na/K/Cl 800mL Solutions Pack	11 04 04 02
2122	EasyLyte Na/K/Li 800mL Solutions Pack	11 04 04 02
2123	EasyLyte Na/K/Ca/pH 800mL Solutions Pack	11 04 04 02
2028	EasyLyte Na/K/Cl/Li 400mL Solution Pack	11 04 04 02
2109	EasyLyte Na/K 400mL Solutions Pack	11 04 04 02
2112	EasyLyte Na/K/Cl 400mL Solutions Pack	11 04 04 02
2115	EasyLyte Na/K/Li 400mL Solutions Pack	11 04 04 02
2114	EasyLyte Na/K/Ca/pH 400mL Solutions Pack	11 04 04 02
2026	EasyLyte Na/K/Cl/Li 800mL Solution Pack	11 04 04 02
2124	EasyLyte Na/K/Cl/Ca-Li 800ml Solutions Pack	11 04 04 02
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04
2843	EasyLyte Quality Control Sample Cups (60)	21 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
2598	EasyLyte Daily Cleaner Cup	21 07 11 02
2108	EasyLyte Solutions Valve	21 07 11 02
2107	EasyLyte Sample Probe	21 07 11 02
2257	EasyLyte Sample Detector	21 07 11 02

EasyLyte Accessories, continued

Catalog No.	Accessory	EDMA Code
2104	EasyLyte Tubing Kit	21 07 11 02
2100	EasyLyte Calcium Tubing Kit	21 07 11 02
2492	EasyLyte Internal Filling Solution (125mL)	11 04 04 90
2309	EasyLyte Wash Solution (50mL)	11 04 04 90
2111	EasyLyte Urine Diluent (500mL)	11 04 04 90
2577	EasyLyte Standard Solution, Urine (50mL)	11 04 04 90
2323	EasyLyte Probe Wipers (6)	21 07 11 02
2541	EasyLyte Printer Paper (3 rolls)	21 07 11 02
2595	EasyLyte EasySampler Sample Cups, 500uL (500)	21 07 11 02
2596	EasyLyte Sample Cups 2.0mL (500)	21 07 11 02
10745	Anti-Evaporation Caps (500)	21 07 11 02
2293	EasyLyte Capillary Tubes	21 07 11 02
2590	EasyLyte Capillary Adaptor Kit	21 07 11 02
2292	EasyLyte Capillary Adaptor Cleaning Kit	21 07 11 02
2578	EasyLyte Red Dye Test Solution (50mL)	11 30 01 11
2572	EasyLyte Troubleshooting Kit	21 07 11 02
2571	EasyLyte Troubleshooting Kit (Na/K/Ca/pH and Na/K/Cl/Li)	21 07 11 02
2105	EasyLyte Quarterly Operating Kit	21 07 11 02
2095	EasyLyte Maintenace Kit	21 07 11 02
2076	EasyLyte Sample Tray	21 07 11 02
2074	EasyLyte Sample Cup Retainer Ring	21 07 11 02
7118	Daily Rinse/Cleaning Solution Kit	11 01 01 27
2544	EasyLyte C Series Printer Paper (5 rolls)	21 07 11 02
2934	EasyLyte Barcode Reader Kit	21 07 11 02

EasyElectrolytes Accessories

Catalog No.	Accessory	EDMA Code
4002	EasyElectrolyte Na/K/Cl Analyzer	21 07 11 02
4003	EasyElectrolyte Na/K/Li Analyzer	21 07 11 02
4102	Reagent Module, Na/K/Cl	11 04 04 02
4103	Reagent Module, Na/K/Li	11 04 04 02
7205	EasyElectrolyte/EasyStat Na+ Electrode	11 04 01 07
7206	EasyElectrolyte/EasyStat K+ Electrode	11 04 01 06
4203	EasyElectrolyte Cl- Electrode	11 04 01 03
4204	EasyElectrolyte Li+ Electrode	11 04 01 04
6204	EasyElectrolyte/EasyStat/EasyBloodGas Reference Electrode	11 04 04 01
4207	EasyElectrolyte Spacer Electrode	11 04 01 90
4301	EasyElectrolyte Troubleshooting Kit	21 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
4402	EasyStat/EasyBloodGas/EasyElectrolyte Red Test Dye Solution	11 30 01 11
4403	EasyElectrolyte Urine Diluent	11 04 04 90
2814	Bi-Level Quality Control Kit	11 50 02 04
2815	Tri-Level Quality Control Kit	11 50 02 04
4405	EasyElectrolyte Na/K/Cl Demonstration Kit	21 07 11 02
4406	EasyElectrolyte Na/K/Li Demonstration Kit	21 07 11 02
4404	EasyElectrolyte Capillary Tube Kit	21 07 11 02
4306	EasyElectrolyte Sampler	21 07 11 02
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 07 11 02
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper	21 07 11 02
4506	EasyElectrolyte Sensor Module	21 07 11 02
4507	EasyElectrolyte Valve Module	21 07 11 02
4508	EasyStat/EasyBloodGas/EasyElectrolyte Compression Plate	21 07 11 02
7302	Probe Wipers	21 07 11 02
4522	EasyElectrolyte Daily Cleaner Sample Cups	21 07 11 02
4539	EasyElectrolyte Sensor Module, Li+	21 07 11 02
6537	EasyElectrolyte/EasyStat/EasyBloodGas Serial Cable, 9-pin	21 07 11 02
6520	EasyElectrolyte/EasyStat/EasyBloodGas Barcode Reader Kit	21 07 11 02

Certificate JP06/040143

The management system of

ERMA INC.

Head Office 2-31-6 Yushima, Bunkyo-ku, Tokyo, 113-0034 Japan

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 November 2018 until 16 November 2021 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 16 November 2021
Issue 9. Certified since 16 November 2006

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 **f** +44 (0)151 350-6600 www.sgs.com

UKAS MANAGEMENT SYSTEMS
0005

HC SGS 13485 2016 0118 M2

ERMA INC.

ISO 13485:2016
EN ISO 13485:2016

Issue 9

Detailed scope

1. Manufacture and service of blood cell counters, spectrophotometric analyzers for IVD use and bilirubin analyzers
2. Distribution of in-vitro diagnostic products for hemoglobin measurement

Additional facilities

Yoshikawa Branch **3-4-8 Kiuri, Yoshikawa-shi, Saitama-ken, 342-0045 Japan**

UKAS MANAGEMENT SYSTEMS
0005

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the quality 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 and service of IVDD General Laboratory Instruments.

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

Certificate Number:
9362-7

Initial Certification Date:
March 28, 2012

Certificate Issue Date:
March 27, 2018

Certificate Expiry Date:
March 27, 2021

SCC Accredited CB-MS
OCSM
Accrédité CCN
TM

Calin Moldovean
President

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