



# 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.**



**Intertek**

**Declaration of Conformity**

**Product identification**  
Product name : Stat-Fax®, Chemistry Analyzer  
Model/Type : P1904

**Manufacturer**  
Name : Awareness Technology, Inc.  
Address : 1935 S.W. Martin Hwy.  
Palm City, Florida 34990  
Country : USA

**Authorized Representative in Europe**  
Representative:  
Name : Emergo Europe  
Address : Prinsessegracht 20  
2514 AP 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:*

*EN 61326-1 / EN 55022  
EN 61010-1*

**Signature**  
Place and Date: Awareness Technology, Inc.  
Signature :   
Name : Steve Andrus  
Quality Manager

December 01, 2003  
Revised May 7<sup>th</sup>, 2018



# Awareness Technology, Inc.

## Declaration of Conformity

### Product identification

Product name : Stat Fax<sup>®</sup> 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 :

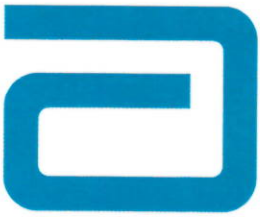
Name :

Steve Andrus  
 Quality Manager

Doug Shields  
 Compliance Engineer

Abbott GmbH & Co KG  
Max-Planck-Ring 2  
D- 65205 Wiesbaden  
Postfach 1303, D-65011 Wiesbaden

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**DATE:** 14<sup>th</sup> December 2015

**TO:** **To whom it may concern**

**FROM:** Paolo Mellino  
Manager Regulatory Affairs Logistics  
Abbott GmbH & Co. KG  
Max-Planck-Ring 2  
65205 Wiesbaden-Delkenheim  
Germany

**SUBJECT:** **Classification of Instrument Parts**

To whom it may concern:

Abbott GmbH & Co KG, Germany, is an authorized representative of Abbott Laboratories that is a worldwide manufacturer of medical equipment, reagents, tests, instruments, and accessories, with additional diagnostic manufacturing plants in the USA and Ireland.

The items listed in Attachment 1 are considered components of accessory kits or spare parts to the ARCHITECT and CELL-DYN instruments.

The spare parts or components of the accessory kit are qualified as part of the respective instrument following the requirements of the IVD Directive 98/79/EC. Therefore these are not considered an IVD device in their own right and do not bear a CE-mark.

For the instruments which are qualified according to the IVD Directive 98/79/EC, a Declaration of Conformity is issued by the manufacturer and the CE-mark is applied, which confirms compliance to the provisions of the directive

Yours sincerely,

Paolo Mellino  
Manager Regulatory Affairs Logistics

Sitz der Gesellschaft: Wiesbaden  
Amtsgericht Wiesbaden HRA 4888  
Persönlich haftende Gesellschafterin:  
Abbott Management GmbH  
Sitz der Gesellschaft: Wiesbaden  
Amtsgericht Wiesbaden HRB 12889

Geschäftsführer:  
Stefan Boll  
John Coulter  
Vorsitzender des Aufsichtsrates:  
Jaime A. Contreras

 **Abbott**  
A Promise for Life

## CELL-DYN Systems

### CELL-DYN 1800

#### Equipment, Parts, Accessories

03H54-01 Accessory Kit (NOTE: For a list of items in the Kit, see the Accessory Kit)  
07H79-01 Interface Specifications  
07H78-01 Keyboard  
92274-01 Aperture Plate WBC  
92264-01 Aperture Plate RBC  
28561-01 Lyse Syringe  
04H36-01 Diluent Syringe  
28514-01 Sample Syringe  
21704-01 Waste Dummy Plug  
93164-01 Sample Probe  
54305-01 Aperture Brush  
20005-01 Printer Cable  
91012-01 Teal Line Filter Isolation  
07H81-01 Bar Code Scanner  
03H96-01 Pull Ring, Solenoid  
99650-01 Code 39 Bar Code Labels  
07H67-01 Lyse Cap for 960 mL container  
09H35-01 Diluent Syringe

#### Accessory Kit (L/N 03H54-01)

1403204 Keyboard Cover  
93501-01 Power Cord  
5406753 Allen Wrench 3/32"  
5406754 Allen Wrench 7/64"  
54305-01 Aperture Brush  
91072-01 Reagent Line Kit  
20005-01 Printer Cable  
9150143 Instructions for Mixing and Handling  
93476-01 Silicon Tubing (S2)

#### Reagent Line Kit (L/N 91072-01)

03H82-01 Reagent Line Assembly, Lyse (1L)  
03H92-01 Detergent Line Inlet Assy  
92161-02 Waste Line Assembly  
92163-01 Diluent Line Inlet Assembly  
92178-01 Lyse Line Inlet Tube

#### Consumables

30005-01 OKIDATA® Graphics Paper  
13401-01 Ribbon OKIDATA® 320  
03H10-04 HP Printer Cartridge (Black)  
99605-02 (International) CELL-DYN Counting Cups  
99606-02 (International) CELL-DYN Counting Cups

**CELL-DYN 3700****Accessories Kit (List Number 06H88-01)**

02H33-01 CD 3700 Interface Specification  
\*1403216 Keyboard Cover  
20005-01 6ft Interface Cable  
21704-01 Waste Sensor Dummy Plug  
\*2400502 Cord Power, 125V  
\*3001008 Computer Printer Paper 8-1/2" X 11"  
\*5100165 Fuse, 8 Amp T (Slo-Blo)  
\*5100201 Fuse Fast, 1.6 Amp  
\*5406754 Allen Wrench, Hex, Short "L" 7  
54305-01 Aperture Brush  
\*5100164 Fuse, 4 Amp T (Slo-Blo)  
70048-01 Allen Wrench  
91482-01 Reagent Line Kit  
91484-01 Peristaltic Pump Tubing- Small  
91485-01 Peristaltic Pump Tubing- Medium  
9212230 Sample Aspiration Tubing (Sample Loader)  
92532-01 Serial Loop Back Device  
03H99-01 CD 3700 SL Needle  
03H96-01 Solenoid Ring Pull  
95519-01 Data Station Cable  
03H98-02 Waste Bottle Cable

**Sample Loader Accessories Kit**

04H91-04 Sample Loader Racks

**Optional Accessories**

25860-01 Bar Code Label Dispenser  
99650-01 Bar Code Tube ID Labels  
99652-01 QC Bar Code Labels  
04H34-01 Syringe, 10 mL  
28561-01 Syringe, 2.5 mL  
28560-01 Syringe, 500 µL  
03H99-01 Needle, Vent/Aspiration  
03H76-01 CELL-DYN 3700 Shear Valve Center Section  
99624-01 Pre-Printed Tickets  
\*Orderable by Abbott personnel only

## **CELL-DYN Ruby**

### **Hardware**

07H40-02 Bar Code Reader, Hand-Held, Trigger Activated  
05H00-02 Display, Flat Panel  
07H96-01 Keyboard  
09H41-01 Mouse  
08H07-01 Printer, Graphics (color laser with USB port connector)  
08H78-16 Printer, Graphics (Color deskjet)  
08H60-05 OKI B4600 220V Printer Mono Laser Printer

### **Accessories Kit List Number 09H04-01**

8952087701\* Cable, Data Station (HSSL)  
09H00-01 Cable, (printer), 10'  
8240051601\* Cable, Power, 6'7"  
06H92-01 Diluent/Sheath Filter  
09H06-01 Needle, SL  
21704-01 Plug, Dummy Waste  
03H96-01 Ring, Pull Solenoids  
92532-01 Serial Loop-Back Device (RS232)  
09H38-02 Tubing, Reagent WBC Lyse  
09H41-01 Mouse, Digital USB  
07H40-02 Bar Code Reader, Handheld, Trigger Activated  
08H43-01 Tubing, Diluent/Sheath  
08H41-01 Tubing, HB Lyse  
02H96-01 Tubing, Waste Outlet

### **Optional Accessories**

07H67-02 Cap (large), Reagent line tubing  
99650-01 Labels  
99652-01 Labels, Bar Code, Q-Labels  
09H31-02 Labels, Bar Code, Background  
06H62-01 Labels, CELL-DYN Rack Bar Code, set of 100  
06H64-01 CELL-DYN Shear Valve Center Section  
04H34-01 Syringe, 10 mL  
28561-01 Syringe, 2.5 mL  
04H40-01 Syringe Kit, 2.5 mL  
28560-01 Syringe, 500 µL  
08H06-01 Kit Rack, Autoloader  
09H32-01 Open Mode Probe  
91485-01 Tubing Set, Transfer Pump  
09H57-01 CDR FAN FLTR ASSY (80mm RIGHT SIDE)  
03H86-01 Check Valve

\*Orderable by Abbott personnel only

### **CELL-DYN Emerald**

#### **Accessories**

09H52-01 Bar Code Scanner  
09H58-01 Emerald Grease (3gm)  
09H54-02 European Power Cord  
09H54-04 Flat Screwdriver/Key  
09H50-01 Diluent Reagent line withcap  
09H51-01 Waste line with cap

#### **Consumables**

03B96-02 Printer paper 8.5 x 11" sheets  
99650-01 Bar Code Labels, Tube ID 1000 labels per roll

## **CELL-DYN Sapphire**

### **Hardware**

08H01-05 CELL-DYN Sapphire Data Station Computer  
07H40-02 Bar Code Reader, Hand-held, Trigger Activated  
08H02-01 Display, Flat Panel 17 inch  
08H02-04 Display, Flat Panel 19 inch  
08H14-01 Keyboard Standard - (Flex style), English  
07H96-02 Keyboard Standard, English  
01H08-01 Mouse Pointing Device  
08H07-08 Printer, Graphics (color laser with USB port connector) 110 VAC  
20825-01 1 Printer, Ticket (with parallel port connector) 110 VAC  
20826-01 1 Printer, Ticket (with parallel port connector) 220 VAC

### **Accessories Kit (List Number 08H03-01)**

54305-01 Brush, Impedance Aperture Made of Camel Hair  
08H08-01 Cable, Data, Analyzer to Data Station  
08H54-01 Cable, Data, Test Interface  
08H53-04 Vent Assembly  
02H63-02 Probe, Sample Aspiration, Nitinol  
92532-01 Serial Loop Back Connector  
02H88-01 Tubing set, Reagent Inlet and Waste Outlet  
02H88-02 Tubing set, Reagent Inlet and Waste Outlet  
91485-01 Tubing set, Sample Transfer Pump  
21704-01 Waste Sensor Plug

### **Optional Accessories**

09H00-01 Cable, USB Printer  
07H67-01 Cap, small, Reagent line tubing  
07H67-02 Cap, large, Reagent line tubing  
99650-01 Labels, Bar Code, Tube ID  
99651-01 Labels, Bar Code, Tube ID  
99652-01 Labels, Bar Code, Q-Labels  
01H59-01 Labels, Bar Code, Q-Labels  
06H62-01 Labels, Bar Code, Rack  
08H06-01 Rack, Autoloader  
08H06-02 Rack, Autoloader  
08H06-04 Rack, Autoloader (Pedia Rack 1)  
08H06-06 Rack, Autoloader (Pedia Rack 2)  
09F99-01 Rack Completion Indicators  
08H13-01 Syringe, Diluent/Sheath, 10mL  
08H49-04 Syringe, Hemoglobin 5mL  
08H46-01 Syringe, Impedance Injection/Metering, 100µL  
08H48-01 Syringe, Reticulocyte Reagent and WBC Reagent – Part A, 2.5mL  
08H47-01 Syringe, Optical Injection/Metering, 500µL  
08H45-01 Syringe, WBC Reagent – Part B, 250µL  
02H90-01 Tubing, Reagent, Diluent/Sheath (Red-striped)  
02H90-02 Tubing, Reagent Diluent/Sheath (clear, no stripes)  
02H91-01 Tubing, Reagent, Hemoglobin  
02H98-01 Tubing, Reagent, WBC – Part A  
02H99-01 Tubing, Reagent, WBC – Part B  
02H96-01 Tubing, Waste Outlet



## ARCHITECT Systems

### **Accessory kit 1 (c4000) - LN 02P68-01**

#### **Installation components**

10 Micron Filter, Water Bath  
High Concentration Waste Tubing Kit  
ICT O-Ring, Probe, and Probe Holder  
Large Cartridge Segment, Inner 02P80-01  
Large Cartridge Segment, Outer (Target) 02P83-01  
Large Cartridge Segment, Outer 02P84-01  
Small Cartridge Segment, Inner 02P79-01  
Small Cartridge Segment, Outer 02P81-01  
Small Cartridge Segment, Inner (Target) 02P82-01  
Reagent Probe 01G47-03  
Reagent Probe Tubing 02P76-01  
Sample Probe 01G48-04  
Sample Probe Tubing 02P77-01  
Sample Wash Solution Carrier 02P78-01  
Waste and Water Tubing Kit

#### **Maintenance components**

10 mm Wrench  
Container, Parts Case  
Cuvette Segment Alignment Tool 02P86-01  
Nozzle, Cleaning Wire 09D50-02  
Phillips Screwdriver  
Slotted Screwdriver

#### **Spare components**

1 mL Syringe 09D41-02  
20 mL reagent Cartridge Adaptor 09D22-12  
Cuvette Dry Tip 09D51-02  
Cuvette Pair Replacement Set 01G46-02  
ICT Probe 09D63-03  
ICT Probe Holder  
Mixer 09D59-02  
Probe Screw, Sample / Reagent  
Reagent Probe 01G47-03  
Reagent Probe Tubing, c4000 02P76-01  
Reagent Syringe O-ring 09D53-02  
Reagent Syringe Seal Tip # 1 09D39-02  
Reagent Syringe Seal Tip # 2 09D40-02  
Sample Probe 01G48-04  
Sample Probe Tubing, c4000 02P77-01  
Sample/Wash Solution Syringe O-ring 09D52-02  
Sample/Wash Solution Syringe Seal Tip #1 09D37-02  
Sample/Wash Solution Syringe Seal Tip #2 09D38-02  
Source Lamp 09D45-02

### **Accessory kit 2 (c4000) - LN 02P73-01**

Carrier Calibration Tool 01P16-01  
Pressure Monitor PCB  
Sample Carriers  
SH Bar code Tool 06E69-01

**Customer maintenance kit (c4000) - LN 02P69-01**

1 mL Syringe 09D41-02  
ICT Reference Solution Check Valve 09D35-02  
Reagent Syringe O-ring 09D53-02  
Reagent Syringe Seal Tip # 1 09D39-02  
Reagent Syringe Seal Tip # 2 09D40-02  
Sample/Wash Solution Syringe O-ring 109D52-02  
Sample/Wash Solution Syringe Seal Tip #1 09D37-02  
Sample/Wash Solution Syringe Seal Tip #2 109D38-02  
Source Lamp 09D45-02

**Accessory kit 1 (c8000) - LN 01G09-02****Installation components**

Power Cable - UL and IEC Plug 02J54-01  
Waste and Water Tubing Kit  
High Concentration Waste Tubing Kit  
ICT Probe 09D63-03  
ICT Probe Holder  
Reagent Probe 01G47-03  
Reagent Probe Tubing 01G47-02  
Sample Probe 01G48-04  
Sample Probe Tubing 01G48-02  
c8000 (R1)/c16000 (R1 and R2) Large Cartridge, Segment A (Target) 04J30-01  
c8000 (R1)/c16000 (R1 and R2) Small Cartridge, Segment A, B, C 01G51-01  
c8000 (R1)/c16000 (R1 and R2) Segment D (Target) 04J32-01  
R2, Small Cartridge, Segment A (target) 04J29-01  
R2, Large Cartridge, Segment B, C, and D 04J31-01  
R2, Small Cartridge, Segment B, C, and D 01G52-01

**Maintenance components**

Phillips Screwdriver  
Slotted Screwdriver  
10 mm Wrench  
c8000 Cuvette Segment Alignment Tool 02J93-01  
Nozzle, Cleaning Wire 09D50-02  
Container, Parts case

**Accessories**

20 mL Reagent Cartridge Adapter 09D22 (-11 or-12)  
Small Reagent Cartridge Adapter 09D22-07

**Spare components**

1 mL Syringe 09D41-02  
Cuvette Dry Tip 09D51-02  
Cuvette Pair Replacement Set 01G46-02  
ICT O-ring 09F93-02  
Mixer 09D59-02  
Reagent Probe 01G47-03  
Reagent Probe Tubing 01G47-02  
Reagent Syringe O-ring 09D53-02  
Reagent Syringe Seal Tip # 1 09D39-02  
Reagent Syringe Seal Tip # 2 09D40-02  
Reagent/Sample Probe Screw 02J51-01  
Sample Probe 01G48-04  
Sample Probe Tubing 01G48-02  
Sample/Wash Solution Syringe O-ring 09D52-02  
Sample/Wash Solution Syringe Seal Tip #1 09D37-02  
Sample/Wash Solution Syringe Seal Tip #2 09D38-02  
Source Lamp 09D45-02

**Customer maintenance kit (c8000) - LN 02J53-01**

1 mL Syringe 209D41-02  
ICT Reference Solution Check Valve 09D35-02  
Reagent Syringe O-ring 09D53-02  
Reagent Syringe Seal Tip # 1 09D39-02  
Reagent Syringe Seal Tip # 2 09D40-02  
Sample/Wash Solution Syringe O-ring 09D52-02  
Sample/Wash Solution Syringe Seal Tip #1 09D37-02  
Sample/Wash Solution Syringe Seal Tip #2 09D38-02  
Source Lamp 09D45-02

**Accessory kit 1 (c16000) - LN 08L71-02****Installation components**

Power Cable - UL and IEC Plug 02J54-01  
Waste and Water Tubing Kit  
High Concentration Waste Tubing Kit  
ICT Probe 09D63-03  
ICT Probe Holder  
Reagent Probe - R1A/R2B (L) 09D48-02  
Reagent Probe - R1B/R2A(r) 09D49-02  
Tubing, Joint to R Probe, R1 & 2A 09D48-05  
Tubing, Joint to R Probe, R1 & 2B 09D49-05  
Sample Probe 01G48-04  
Sample Probe Tubing 01G48-02  
c8000 (R1)/c16000 (R1 and R2) Large Cartridge, Segment A (Target) 04J30-01  
c8000 (R1)/c16000 (R1 and R2) Large Cartridge, Segment A, B, C 04J33-01  
c8000 (R1)/c16000 (R1 and R2) Segment D (Target) 04J32-01  
10 micron filter, waterbath

**Maintenance components**

Phillips Screwdriver  
Slotted Screwdriver  
10 mm Wrench  
c16000 Cuvette Segment Alignment Tool 08L73-01  
Nozzle Cleaning Wire 09D50-02  
Container, Parts case

**Accessories**

20 mL Reagent Cartridge Adapter 09D22 (-11 or-12)  
Small Reagent Cartridge Adapter 09D22-07

**Spare components**

1 mL Syringe 09D41-02  
Cuvette Dry Tip 09D51-02  
Cuvette Pair Replacement Set 09D33-03  
ICT O-ring 09F93-02  
Peristaltic Pump Tubing Kit  
Mixer 09D59-02  
Pipettor Arm Cover Screw 09D46-20  
Reagent Probe R1A/R2B 09D48-02  
Reagent Probe R1B/R2A 09D49-02  
Reagent Probe Screw 09D48-10  
Tubing, Joint to R Probe, R1 & 2A 09D48-05  
Tubing, Joint to R Probe, R1 & 2B 09D49-05  
Reagent Syringe O-ring 09D53-02  
Reagent Syringe Seal Tip # 1 09D39-02  
Reagent Syringe Seal Tip # 2 09D40-02  
Sample Probe 01G48-04  
Sample Probe Tubing 01G48-02  
Probe Screw, c8000 (Reagent and Sample)/c16000 (Sample) 02J51-01  
Sample/Wash Solution Syringe O-ring 09D52-02  
Sample/Wash Solution Syringe Seal Tip #1 09D37-02  
Sample/Wash Solution Syringe Seal Tip #2 09D38-02  
Source Lamp 09D45-02

**Customer maintenance kit (c16000) - LN 08L72-01**

1 mL Syringe 09D41-02

ICT Reference Solution Check Valve 09D35-02

Reagent Syringe O-ring 09D53-02

Reagent Syringe Seal Tip # 1 09D39-02

Reagent Syringe Seal Tip # 2 09D40-02

Sample/Wash Solution Syringe O-ring 09D52-02

Sample/Wash Solution Syringe Seal Tip #1 09D37-02

Sample/Wash Solution Syringe Seal Tip #2 09D38-02

Source Lamp 09D45-02

**ARCHITECT i System accessory kits - LN 08C94-01 (i2000), LN 03M77-01 (i2000SR), and LN 01L87-01(i1000SR)**

**i2000 and i2000SR components - LN 08C94-01 and LN 03M77-01**

Bag, Biohazard

External Waste Tubing

Filter, Card Cage/Supply 08C94-07

Filter, Processing Center 08C94-14

Inlet assembly, buffer Maintenance Kit

• Bar Code Calibration Tool 06E67-01

• Carrier Calibration Tool 05E13-01

• Flashlight

• Fuse Kit

• Grease

• Lens Paper

• Maintenance Cleaning Bottle 02G16-99

• Optics Cap

• WZ Probe Maintenance Water Bottle 06E68-01

• Screwdriver #1 Phillips

• Screwdriver #2 Phillips

• SH Bar Code Tool 06E69-01

• Thermistor Removal Wrench

• Valve Removal Tool

Power cord kit

Probe, Wash Zone 08C94-35

Probe (Sample/Reagent) 08C94-42

Probe/Tubing, Waste Arm 08C94-89

Sensor, Level, Buffer 08C94-25

Sensor, Level, Trigger 08C94-26

Sensor, Level, Pre-Trigger 08C94-27

Tubing/Sensor, Temp, WZ 08C94-87

Tubing, Wash Buffer Transfer 08C94-21

Wash Buffer Preparation Container 08C94-56

Wash Buffer Reservoir

**i2000 components - LN 08C94-01**

Internal component cover 1 06E27-10

Internal component cover 2 & 3 06E27-20

Internal component cover 4 (i2000 accessory kit only) 06E27-30

Internal component cover 5 (i2000 accessory kit only) 06E27-40

Internal component cover 6 (i2000 accessory kit only) 06E27-50

Internal component cover 7 (i2000 accessory kit only) 06E27-60

Internal component cover 8 (i2000 accessory kit only) 06E27-70

**i2000SR components - LN 03M77-01**

STAT Probe Tubing (i2000SR accessory kit only) 03M77-49

Internal component cover 1 06E27-11

Internal component cover 2 & 3 06E27-21

Internal component cover 4 (i2000SR accessory kit only) 02J63-14

Internal component cover 5 (i2000SR accessory kit only) 02J63-15

Internal component cover 6 (i2000SR accessory kit only) 02J63-16

Internal component cover 7 (i2000SR accessory kit only) 02J63-17

**ARCHITECT i1000SR components - LN 01L87-01**

Bag, Biohazard

Bleach Preparation Container 08C94-63

Buffer filter 08C94-29

Buffer outlet assembly 01P12-01

Card cage/SCC door filter 03L99-01

Card cage filter 06L00-01

External Waste Tubing

Internal Decon Extension Tubing/Cable Kit 01P83-01

Maintenance Kit:

- Bar Code Calibration Tool 06E67-01

- Buffer Reservoir Cap

- Carrier Calibration Tool 01P16-01

- Flashlight

- Fuse Kit

- Lens Paper

Maintenance Cleaning Bottle 02G16-99

- Optics Cap

- WZ Probe Maintenance Water Bottle 06E68-01

- Screwdriver #1 Phillips

- Screwdriver #2 Phillips

- SH Bar Code Tool 06E69-01

- Thermistor Removal Wrench

- Valve Removal Tool

- Ground strap

- O-ring Removal Tool Probe (Sample/Reagent) 08C94-42

Probe, Wash Zone 08C94-35

Reagent Carriers

Sample Carriers

Sensor, Level, Buffer 06L01-01

Sensor, Level, Pre-Trigger 8C94-27

Sensor, Level, Trigger 8C94-26

Tubing, Probe 06L04-01

Tubing/Sensor, Temp, WZ 08C94-87

Tubing, Wash Buffer Transfer 08C94-21

Unloader

Wash Cup Baffle 01P41-01

Wash Buffer Preparation Container 08C94-56

Wash Buffer Reservoir 06L06-01

Waste pressure switch to floor tubing

**Additional accessories**

Alternate c8000/c16000 Reagent Supply Center Segments:

- c8000 (R1)/c16000 (R1 and R2) Large Cartridge, Segment A, B, C 04J33-01

- R2, large cartridge, segments B, C, and D 04J31-01

- R2, small cartridge, segments B, C, and D1 01G52-01

Alternate c4000 Reagent Supply Center Segments:

- Large Cartridge Segment, Inner 02P80-01

- Large Cartridge Segment, Outer 02P84-01

- Large Cartridge Segment, Outer (Target) 02P83-01

- Small Cartridge Segment, Inner 02P79-01

- Small Cartridge Segment, Outer 02P81-01

- Small Cartridge Segment, Inner (Target) 02P82-01

ARCHITECT ARM (Automated Reconstitution Module) accessory 08C95-89

Cuvette Segment (c4000) 02P75-01

Cuvette Segment (c8000) 01G46-01

Cuvette Segment (c16000) 09D32-05

External Waste Pump:

- i2000/i2000SR 08C94-19

- c System 09D61-03

High Concentration Waste Bottle 03E50-26

High Concentration Float Switch Cable 03E50-31

LAS Sample Carousel ID Labels (i2000) sheet 08C96-25

LAS Sample Carousels (*i*2000) 08C96-07  
Liquid Waste Container (*i*1000SR) 06L05-01  
Pump Poppet Valve Set (*c* System) 09D36-02  
Reagent carriers (*i*1000SR) 08L20-01  
RSH Sample Carrier Trays 04J49-01  
Sample Carousel (*c*8000/*c*16000) 02J50-01  
Sample Carousel Clip (*c*8000/*c*16000) 04J45-01  
Sample Carriers 05E15-01  
Thermometer, External (*i* System) 08C94-88  
Tubing, probe (*i*2000/*i*2000SR) 08C94-49

### **SCC components**

#### **Required**

Keyboard:

- English Keyboard 07D11-01
- English Keyboard (black) 07D11-02
- French Keyboard 07D11-20
- French Keyboard (black) 07D11-22
- German Keyboard 07D11-30
- German Keyboard (black) 07D11-32
- Italian Keyboard 07D11-40
- Italian Keyboard (black) 07D11-42
- Spanish Keyboard 07D11-50
- Spanish Keyboard (black) 07D11-52

Monitor - Touchscreen Flatscreen 07D03-15

Monitor - Touchscreen LCD (dark gray) 07D03-22

Mouse 07D01-99

Mouse (black) 07D02-01

Network HUB (USB Powered) 07D04-60

#### **Optional**

Bar Code Scanner 07D09-02

Component Stand 09D19-01

Printer:

• Printer (110V) 07D08-11

• Printer (220V) 07D08-22

UPS for SCC only:

• UPS 110V 07D06-11

• UPS 220V 07D06-22

**DICHIARAZIONE DI CONFORMITÀ CE**  
**EC DECLARATION OF CONFORMITY**

conforme all'Allegato III della Direttiva 98/79/CE "Dispositivi Medico-Diagnostici In Vitro" e s.m.i.  
according to Annex III of the Directive 98/79/EC on "In Vitro Diagnostic Medical Devices" as amended

fabbricante  
manufacturer

**VACUTEST KIMA S.r.l. - articoli per laboratori analisi**  
**disposable labware**

indirizzo  
address

**Via dell'Industria, 12**  
**35020 Arzergrande (PD) - Italia**

telefono  
phone

**+39-049-9720624**

fax  
fax

**+39-049-9720182**

posta elettronica  
e-mail

**info@vacutestkima.it**

identificazione dei prodotti  
product identification

**Autoanalizzatore per provette KIMASED**  
**KIMASED Tubes AUTOANALYZER**

nome commerciale  
brand name

**"KIMASED AUTO 60" "KIMASED AUTO 20"**

classificazione dei prodotti  
product classification

**dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.**  
**devices other than those mentioned in Annex II of the Directive 98/79/EC as amended**

**Si dichiara**

sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. "Dispositivi Medico-Diagnostici In Vitro".

Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

**Hereby we declare**

*under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on "In Vitro Diagnostic Medical Devices".*

All the supporting documents, as required by Annex III of the 98/79/EC Directive, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data  
place and date

**Arzergrande, 02/09/2013**

firma  
signature

**Assicuratore Qualità / Quality Manager**  
**Giovanni Chiarin**

*Giovanni Chiarin*





## EC Declaration of Conformity

*EG Konformitätserklärung*

Document No. **DOC0711295**

*Manufacturer/ Hersteller:*

**GE Medical Systems  
Information Technologies**

8200 West Tower Avenue  
Milwaukee, WI 53223 USA

*Authorized EU Representative/ EU Repräsentant:*

**GE Medical Systems Information  
Technologies GmbH**

Munzingerstrasse 5  
79111 Freiburg, Germany

We herewith declare that the product/ *Wir erklären hiermit, dass das Produkt*

**MAC 600**

(including system components and accessories/*einschließlich Systemkomponenten und Zubehör*)

UMDNS-Code: 11411; GMDN-Code: 11-411

fulfills the requirements of the following directives, standards and normative documents:  
*mit den folgenden Richtlinien, Normen und normativen Dokumenten übereinstimmt:*

1. *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices*
2. *EN 60601-1:1990, A1:1993, A2:1995; Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance*
3. *EN 60601-1-1:2001; Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems*
4. *EN 60601-1-2:2001, A1:2006 (IEC 60601-1-2:2004); Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests*
5. *EN 60601-2-25: 1995, A1:1999; Medical Electrical Equipment – Part 2-25: Particular Requirements for the safety of electrocardiographs*
6. *EN 60601-1-4:1996, A1:1999 (IEC 60601-1-4:2000); Medical Electrical Equipment – Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems*
7. *EN 60601-2-51: 2003; Medical Electrical Equipment – Part 2-51; Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs*
8. *EN 60601-1-6; 2007; Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard Usability*

Compliance of the designated product with the Directive 93/42/EEC has been certified by:

*Die Übereinstimmung des bezeichneten Produktes mit der Richtlinie 93/42/EWG wird bescheinigt durch:*

**GE Medical Systems Information Technologies**

8200 West Tower Avenue  
Milwaukee, WI 53223 USA

**Technical Dossier CE-A-005**

The medical device has been assigned to class **<IIa>** as specified in the Directive 93/42/EEC. It bears the mark

# GE Healthcare

Das Medizinprodukt ist eingestuft in die Klasse <IIa> gemäss der Richtlinie 93/42/EWG, es trägt die Kennzeichnung

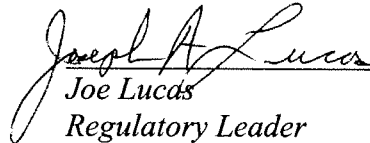


The designated product has been designed and manufactured under a quality management system according to EN ISO 13485: 2003 and Annex II of Directive 93/42/EEC concerning medical devices. The conformity of the quality management system has been certified by:

*Das bezeichnete Produkt wurde unter Anwendung des Qualitätsmanagementsystems gemäss ISO 13485:2003 und Anhang II der Richtlinie 93/42/EWG über Medizinprodukte entwickelt, hergestellt und geprüft. Die Konformität des Qualitätsmanagementsystems wird bescheinigt durch:*

G-MED France

 Jan 15, 2010  
Date  
Dave Wahlig  
Director, Regulatory Affairs  
Wauwatosa, Wisconsin

 Jan. 15, 2010  
Date  
Joe Lucas  
Regulatory Leader  
Wauwatosa, Wisconsin

The technical documentation is filed at Research Park, Wauwatosa, WI  
Die technische Dokumentation ist archiviert bei Research Park, Wauwatosa, WI

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Medica Corporation

(FIN F002402)

Main Site: 5 Oak Park Drive, Bedford, Massachusetts, 01730, United States

Additional Site: 3 Oak Park Drive, Bedford, Massachusetts, 01730, United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

### ISO 13485:2016

**Brazil:** Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

**Canada:** Medical Devices Regulations – Part 1- SOR 98/282

**United States:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

**Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

### The management system is applicable to:

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

**Certificate Number:**

0089217-01

**Initial Certification Date:**

2019-04-19

**Date of Certification Decision:**

2022-03-24

**Certification Effective Date:**

2022-04-18

**Certification Expiry Date:**

2025-04-18



intertek

**Calin Moldovean**

President, Business Assurance

Intertek Testing Services NA, Inc.  
900 Chelmsford Street  
Lowell, MA, USA 01851





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

*Products For Health Care*

## Declaration of Conformity

### Product Name:

EasyLyte and accessories per attachment

EasyElectrolyte and accessories per attachment

EasyStat and accessories per attachment

EasyBloodGas and accessories per attachment

### Model/Type:


EasyLyte Na/K, Na/K/Cl, Na/K/Li, Na/K/Cl/Li, Na/K/Ca/pH

EasyElectrolyte Na/K/Cl, Na/K/Li

pH/pCO<sub>2</sub>/pO<sub>2</sub>/Na/K/Ca/Hct, pH/pCO<sub>2</sub>/pO<sub>2</sub>/Na/K/Cl/Hct

pH/pCO<sub>2</sub>/pO<sub>2</sub>

### Manufacturer

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

### Representative

 Emergo Europe, Molenstraat 15  
NL-2513 BH 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 in conformity with the Annex III, essential requirements and provisions of council Directive: 98/79/EC

**Place and Date:** Bedford, Massachusetts, USA, March 1, 2012

### Signature:



**Name:** Photios Makris

**Title:** Director of Regulatory Affairs

**EasyBloodGas and EasyStat Accessories**

<b>Catalog No.</b>	<b>Accessory</b>	<b>EDMA Code</b>
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 10
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 Kit	11 01 01 27
6402	Red Test Dye Solution	11 70 31 90
6503	EasyBloodGas Capillary Tube Kit	21 04 10 01
6603	EasyBloodGas Demonstration Kit	21 04 10 01
6306	EasyBloodGas Sampler	21 04 10 01
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 04 10 01
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper (5 rolls)	21 04 10 01
6506	EasyBloodGas Sensor Module	21 04 10 01
6507	EasyStat/EasyBloodGas Valve Module	21 04 10 01
6508	Compression Plate	21 04 10 01
6518	Serial Cable, 25-pin	21 04 10 01
6537	Serial Cable, 9-pin	21 04 10 01
6520	Barcode Reader Kit	21 04 10 01
7101	EasyStat Reagent Module	11 70 31 10
7205	EasyStat/EasyElectrolyte Na Electrode	11 04 01 07
7206	EasyStat/EasyElectrolyte 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 04 10 01
7309	Bi-Level Hematocrit Quality Control	13 01 70 03
7603	EasyStat Demonstration Kit	21 04 10 01
7303	EasyStat/EasyBloodGas Capillary Tube Kit	21 04 10 01
7306	EasyStat Sampler	21 04 10 01
7304	EasyStat Pump Tube	21 04 10 01
7506	EasyStat Sensor Module	21 04 10 01
7302	Probe Wipers	21 04 10 01

## EasyElectrolyte Accessories

Catalog No.	Accessory	EDMA Code
4102	EasyElectrolyte Reagent Module Na/K/Cl	11 03 01
4103	EasyElectrolyte Reagent Module Na/K/Li	11 03 01
7205	EasyStat/EasyElectrolyte Na Electrode	11 04 01 07
7206	EasyStat/EasyElectrolyte K Electrode	11 04 01 06
4203	EasyElectrolyte Cl Electrode	11 04 01 03
4204	EasyElectrolyte Li Electrode	11 04 01 04
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode	11 04 04 01
4207	EasyElectrolyte Spacer Electrode	11 04 01 90
4301	EasyElectrolyte Troubleshooting Kit	21 04 10 01
2118	Daily Cleaning Solution Kit	11 01 01 27
4402	Red Test Dye Solution	11 70 31 90
4403	EasyElectrolyte Urine Diluent	11 04 04 90
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04
4405	EasyElectrolyte Demonstration Kit, Na/K/Cl	21 04 10 01
4406	EasyElectrolyte Demonstration Kit, Na/K/Li	21 04 10 01
4404	EasyElectrolyte Capillary Tube Kit	21 04 10 01
4306	EasyElectrolyte Sampler	21 04 10 01
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 04 10 01
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper (5 rolls)	21 04 10 01
4506	EasyElectrolyte Sensor Module	21 04 10 01
4507	EasyElectrolyte Valve Module	21 04 10 01
4508	Compression Plate	21 04 10 01
7302	Probe Wipers	21 04 10 01
4522	EasyElectrolyte Daily Cleaner Sample Cups	21 04 10 01
4539	EasyElectrolyte Sensor Module, Li	21 04 10 01
6518	Serial Cable, 25-pin	21 04 10 01
6537	Serial Cable, 9-pin	21 04 10 01
6520	Barcode Reader Kit	21 04 10 01

## EasyLyte Accessories

Catalog No.	Accessory	EDMA Code
2070	EasyLyte EasySampler	21 04 10 01
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 04 10 01
2120	EasyLyte Na/K 800mL Solutions Pack	11 03 01
2121	EasyLyte Na/K/Cl 800mL Solutions Pack	11 03 01
2122	EasyLyte Na/K/Li 800mL Solutions Pack	11 03 01
2123	EasyLyte Na/K/Ca/pH 800mL Solutions Pack	11 03 01
2028	EasyLyte Na/K/Cl/Li 800mL Solutions Pack	11 03 01
2109	EasyLyte Na/K 400mL Solutions Pack	11 03 01
2112	EasyLyte Na/K/Cl 400mL Solutions Pack	11 03 01
2115	EasyLyte Na/K/Li 400mL Solutions Pack	11 03 01
2114	EasyLyte Na/K/Ca/pH 400mL Solutions Pack	11 03 01
2026	EasyLyte Na/K/Cl/Li 400mL Solutions Pack	11 03 01
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 04 10 01
2118	Daily Cleaning Solution Kit	11 01 01 27
2598	EasyLyte Daily Cleaner Cup	21 04 10 01
2108	EasyLyte Solutions Valve	21 04 10 01
2107	EasyLyte Sample Probe	21 04 10 01
2257	EasyLyte Sample Detector	21 04 10 01
2104	EasyLyte Tubing Kit	21 04 10 01
2100	EasyLyte Calcium Tubing Kit	21 04 10 01
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 04 10 01
2541	EasyLyte Printer Paper (3 rolls)	21 04 10 01

**EasyLyte Accessories, continued**

<b>Catalog No.</b>	<b>Accessory</b>	<b>EDMA Code</b>
2595	EasyLyte EasySampler Sample Cups, 500uL (500)	21 04 10 01
2596	EasyLyte Sample Cups 2.0mL (500)	21 04 10 01
10745	Anti-Evaporation Caps (500)	21 04 10 01
2293	EasyLyte Capillary Tubes	21 04 10 01
2590	EasyLyte Capillary Adaptor Kit	21 04 10 01
2292	EasyLyte Capillary Adaptor Cleaning Kit	11 04 04 90
2578	EasyLyte Red Dye Test Solution (50mL)	11 04 04 90
2572	EasyLyte Troubleshooting Kit	21 04 10 01
2571	EasyLyte Troubleshooting Kit (Na/K/Ca/pH and Na/K/Cl/Li)	21 04 10 01
2105	EasyLyte Quarterly Operating Kit	21 04 10 01
2095	EasyLyte Maintenance Kit	21 04 10 01
2076	EasyLyte Sample Tray	21 04 10 01
2074	EasyLyte Sample Cup Retainer Ring	21 04 10 01
7118	Daily Rinse/Cleaning Solution Kit	11 01 01 27
2544	EasyLyte C Series Printer Paper (5 rolls)	21 04 10 01

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