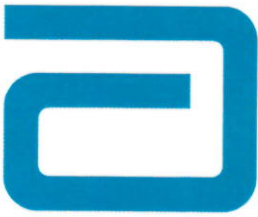


Abbott GmbH & Co KG
Max-Planck-Ring 2
D- 65205 Wiesbaden
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Tel. +49 61 22 58 0
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DATE: 14th December 2015

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



Customer Service Organization Certificate of Technical Competence

This is to acknowledge that

Ion Negru

has met Abbott's Service Certification Criteria for

CELL-DYN Ruby Field Service Certification Exam

Certificate is valid for two years from printed completion date

29/06/2018

Manager

I certify that this individual has completed the program requirements

I certify that on the dates above, this individual has completed the program requirements for Instrument Certification

Abbott Diagnostics Division

Abbott Laboratories 2016



Customer Service Organization Certificate of Technical Competence

This is to acknowledge that

Sergiu Sorocovici

has met Abbott's Service Certification Criteria for

CELL-DYN Ruby Field Service Certification Exam

Certificate is valid for two years from printed completion date

29/06/2018

Manager

I certify that this individual has completed the program requirements

I certify that on the dates above, this individual has completed the program requirements for Instrument Certification

Abbott Diagnostics Division

Abbott Laboratories 2016



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
 Quality Manager

Chris Mauer
 Compliance Engineer

Title :



Awareness Technology, Inc.



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 7th, 2018



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



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

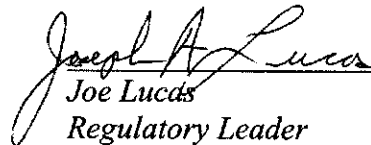


The designated product has been designed and manufactured under a quality management system according to EN ISO 13485: 2003 and Annex II of Directive 93/42/EEC concerning medical devices. The conformity of the quality management system has been certified by:

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

Training on Centrifuging Technology

Mr /-Ms

Sergiu Sorocovici

Global Biomarketing Group

str. Tighina 65, of. 607

2001 Chisinau, Moldau

has attended a 2-days training on Hettich centrifuges from
April 12th – April 13th, 2011

Tuttlingen, 13.04.2011

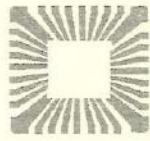
Place, Date

i.A.

Danuta Klaus

Training Supervisor

**Andreas Hettich
GmbH & Co. KG**
Föhrenstr. 12, 78532 Tuttlingen
Postfach 2 60, 78503 Tuttlingen
Telefon (07461) 705-0
Telefax (07461) 705-125



Awareness Technology, Inc.
Certificate of Training

Eng. Sergiu Sorocovici
Global Biomarketing Group

Chisinau, Moldova

has successfully completed a comprehensive course of training for the applications, operation,
technical service and repairs of the

ChemWell® Automated EIA/Chemistry Analyzer

Awareness Technology manufactured instrument.

On this 20th day of November, 2007

Serg Sorocovici

Signature

November 20, 2007

Date



Training certificate

helena
Biosciences Europe

This is to certify that

Sergeu Sorokovice

from

IM Global Biomarketing Group

has received training on the following:

Electrophoresis products: SAS-1/2

Haemostasis products: C-series, AC-4, AggRAM and reagents

Service training: AC-4

Signed:



Date: 31st October - 4th November 2011

Tel +44 (0)191 482 8440

info@helena-biosciences.com

Queensway South, Team Valley Trading Estate,

Fax +44 (0)191 482 8442

techsupport-hs@helena-biosciences.com

Gateshead, Tyne and Wear, NE11 0SD, United Kingdom

www.helena-biosciences.com



CERTIFICATE OF TRAINING

THIS CERTIFIES THAT

Sergiu Sorocovici

HAS SUCCESSFULLY COMPLETED THE TRAINING COURSE

Alinity I Service

August 1st – August 5th 2022

Athanasios Sakis Plakas

TRAINER NAME

ABBOTT DIAGNOSTICS

TRAINER SIGNATURE

A handwritten signature in blue ink, appearing to be 'Athanasios Plakas', is written over a faint background watermark of the Abbott logo.

05.08.2022

DATE DD.MM.YYYY

GERMANY - WIESBADEN