

Declaration of Conformity

Certificate Identification: SC-08H59
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08H59-01	55866	CELL-DYN 26 Plus Control, Full Pack	Self-declared
08H59-02	55866	CELL-DYN 26 Plus Control, Half Pack	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: 

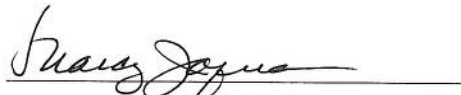
Full Name: Barry Simpson

Position: Site Quality Manager

Date of Approval: 18 June 2015

Date Issued: JUN 30 2015

Supersedes: IRIS V5
February 26, 2015

Signature: 

Full Name: Marcy Jaqua

Position: Director, Regulatory Affairs

Date of Approval: 30 June 2015

Place Issued: Abbott Santa Clara

Effective (Date or Lot Number): JUL 06 2015

Declaration of Conformity

Certificate Identification: SC-01H73
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
01H73-01	58237	CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/SHEATH	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

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This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: 

Full Name: Barry Simpson

Position: Site Quality Manager

Date of Approval: 29 Jun 2015

Date Issued: JUN 30 2015

Supersedes: IRIS V2
January 10, 2014

Signature: 

Full Name: Marcy Jaqua

Position: Director, Regulatory Affairs

Date of Approval: 30 June 2015

Place Issued: Abbott Santa Clara

Effective (Date or Lot Number): JUL 06 2015

Declaration of Conformity

Certificate Identification: SC-99644
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
99644-01	59058	CELL-DYN ENZYMATIC CLEANER CONCENTRATE	Self-declared
93641-01	59058	CELL-DYN ENZYMATIC CLEANER CONCENTRATE	Self-declared

Authorized European Representative (name and address)	ABBOTT Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 USA
Harmonized Standards	Listed in the Technical Documentation

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This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Quality Manager	Position:	Regulatory Affairs, Director
Date of Approval:	04. Sept. 2015	Date of Approval:	04 Sep 2015
Date Issued:	SEP 04 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V4, January 10, 2014	Effective (Date or Lot Number):	SEP 11 2015

Declaration of Conformity

Certificate Identification: SC-03H80

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

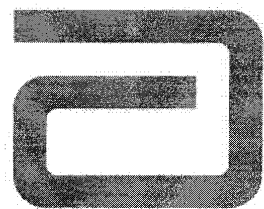
List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
03H80-02	61165	CELL-DYN Ruby, CELL-DYN 3200 Systems CN-FREE HGB/NOC LYSE	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

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This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: <u></u> Full Name: <u>Barry Simpson</u> Position: <u>Site Quality Manager</u> Date of Approval: <u>29 Jun. 2015</u> Date Issued: <u>JUN 30 2015</u> Supersedes: <u>IRIS V2</u> <u>January 10, 2014</u>	Signature: <u></u> Full Name: <u>Marcy Jaqua</u> Position: <u>Director, Regulatory Affairs</u> Date of Approval: <u>30 June 2015</u> Place Issued: <u>Abbott Santa Clara</u> Effective (Date or Lot Number): <u>JUL 06 2015</u>
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Abbott

A Promise for Life

This document certifies that:

Sergiu Sorocovici

has completed

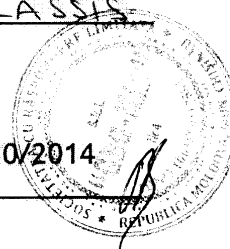
Ruby

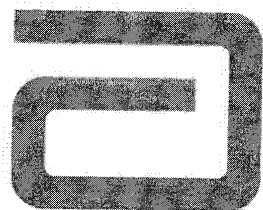
Service Training

TSOBANIDIS VLASSIS

Trainer.....

Athens, 29-31/10/2014





Abbott

A Promise for Life

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has completed

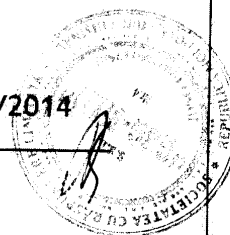
Ruby

Service Training

TSOBANIDIS VLASSIS

Trainer.....

Athens, 29-31/10/2014



Declaration of Conformity

Certificate Identification: SC-08H52
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08H52-01	61165	CELL-DYN Ruby, CELL-DYN 3200 Systems WBC LYSE	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

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Signature: <u></u> Full Name: <u>Barry Simpson</u> Position: <u>Site Quality Manager</u> Date of Approval: <u>29. Jun. 2015</u> Date Issued: <u>JUN 30 2015</u> Supersedes: <u>IRIS V2,</u> <u>January 10, 2014</u>	Signature: <u></u> Full Name: <u>Marcy Jaqua</u> Position: <u>Director, Regulatory Affairs</u> Date of Approval: <u>30 June 2015</u> Place Issued: <u>Abbott Santa Clara</u> Effective (Date or Lot Number): <u>JUL 06 2015</u>
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