

Declaration of Conformity



Certificate Identification: SC-08H59
Legal Manufacturer's Name: Abbott Laboratories
Diagnosics 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: 	Signature: 
Full Name: <u>Barry Simpson</u>	Full Name: <u>Marcy Jaqua</u>
Position: <u>Site Quality Manager</u>	Position: <u>Director, Regulatory Affairs</u>
Date of Approval: <u>18 June 2015</u>	Date of Approval: <u>30 June 2015</u>
Date Issued: <u>JUN 30 2015</u>	Place Issued: <u>Abbott Santa Clara</u>
Supersedes: <u>IRIS V5</u> <u>February 26, 2015</u>	Effective (Date or Lot Number): <u>JUL 06 2015</u>

Declaration of Conformity



Certificate Identification: SC-01H73
Legal Manufacturer's Name: Abbott Laboratories
Diagnosics 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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Signature:		Signature:	
Full Name:	<u>Barry Simpson</u>	Full Name:	<u>Marcy Jaqua</u>
Position:	<u>Site Quality Manager</u>	Position:	<u>Director, Regulatory Affairs</u>
Date of Approval:	<u>29 Jun. 2015</u>	Date of Approval:	<u>30 June 2015</u>
Date Issued:	<u>JUN 30 2015</u>	Place Issued:	<u>Abbott Santa Clara</u>
Supersedes:	<u>IRIS V2</u> <u>January 10, 2014</u>	Effective (Date or Lot Number):	<u>JUL 06 2015</u>

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:  Full Name: <u>Barry Simpson</u> Position: <u>Quality Manager</u> Date of Approval: <u>04. Sept. 2015</u> Date Issued: <u>SEP 04 2015</u> Supersedes: <u>IRIS V4, January 10, 2014</u>	Signature:  Full Name: <u>Marcy Jaqua</u> Position: <u>Regulatory Affairs, Director</u> Date of Approval: <u>04 Sep 2015</u> Place Issued: <u>Abbott Santa Clara</u> Effective (Date or Lot Number): <u>SEP 11 2015</u>
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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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Full Name: <u>Barry Simpson</u>	Full Name: <u>Marcy Jaqua</u>
Position: <u>Site Quality Manager</u>	Position: <u>Director, Regulatory Affairs</u>
Date of Approval: <u>29 Jun. 2015</u>	Date of Approval: <u>30 June 2015</u>
Date Issued: <u>JUN 30 2015</u>	Place Issued: <u>Abbott Santa Clara</u>
Supersedes: <u>IRIS V2</u> <u>January 10, 2014</u>	Effective (Date or Lot Number): <u>JUL 06 2015</u>

Declaration of Conformity



Certificate Identification: SC-08H52
Legal Manufacturer's Name: Abbott Laboratories
Diagnosics 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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Position: <u>Site Quality Manager</u>	Position: <u>Director, Regulatory Affairs</u>
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Date Issued: <u>JUN 30 2015</u>	Place Issued: <u>Abbott Santa Clara</u>
Supersedes: <u>IRIS V2, January 10, 2014</u>	Effective (Date or Lot Number): <u>JUL 06 2015</u>