

Declaration of Conformity

Certificate Identification:	<u>SC-08H67</u>
Legal Manufacturer's Name:	<u>Abbott Laboratories</u>
Legal Manufacturer's Address:	<u>Diagnostics Division</u>
	<u>Abbott Park, IL 60064 USA</u>

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08H67-01	35476	CELL-DYN Ruby	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 and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011, 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: <u>Eric Rowsey</u> Position: <u>Director of Quality</u> Date of Approval: <u>8/18/2016</u> Date Issued: <u>AUG 25 2016</u> Supersedes: <u>N/A</u>	Signature:  Full Name: <u>Rosemarie Lulu</u> Position: <u>Regulatory Affairs Project Manager</u> Date of Approval: <u>30 JUL 2016</u> Place Issued: <u>Abbott Santa Clara</u> Effective (Date or Lot Number): <u>AUG 29 2016</u>
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Certificate Identification: SC-08H67
Abbott Laboratories
Legal Manufacturer's Name: 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
08H67-01	35476	CELL-DYN Ruby	Self-declared
08H67-03	35476	CELL-DYN Ruby	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>Eric Rowsey</u>	Full Name:	<u>Mirna DiPano</u>
Position:	<u>Director of Quality</u>	Position:	<u>Director of Regulatory Affairs</u>
Date of Approval:	<u>12-28-2016</u>	Date of Approval:	<u>Jan 03, 2017</u>
Date Issued:	<u>JAN 04 2017</u>	Place Issued:	<u>Abbott Santa Clara</u>
Supersedes:	<u>IRIS V7 August 29, 2016</u>	Effective (Date or Lot Number):	<u>JAN 06 2017</u>