

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	ABBOTT	
Representative	Max-Planck-Ring-2	
(Name and Address)	65205 Wiesbaden, Germany	
Storage site of technical	Abbott Laboratories	***
documentation	4551 Great America Parkway	
(Name and Address)	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.

Signature:	Barn Cos	Signature:	Tuara Jagua
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	18. June , 2015	Date of Approval:	30 June 2015
Date Issued:	JUN 30 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V5 February 26, 2015	Effective (Date or Lot Number):	JUL 0 6 2015



Certificate Identification: SC-01H73

Abbott Laboratories
Legal Manufacturer's Name: Diagnostics Division

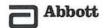
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

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

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

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Barry Spor	Signature:	Mais Jagur
Barry Simpson	Full Name:	Marcy Jaqua
Site Quality Manager	Position:	Director, Regulatory Affairs
29. Jun. 2015	Date of Approval:	30 June 2015
JUN 3 0 2015	Place Issued:	Abbott Santa Clara
IRIS V2 January 10, 2014	Effective (Date or Lot Number):	JUL 0 6 2015
	Barry Simpson Site Quality Manager  29. Two. 2015  JUN 30 2015  IRIS V2	Barry Simpson Full Name:  Site Quality Manager Position:  29. Zwo. 2015 Date of Approval:  JUN 30 2015 Place Issued:  IRIS V2 Effective (Date or



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	ABBOTT	
Representative (name and	Max-Planck-Ring 2	
address)	65205 Wiesbaden, Germany	
Storage site of technical	Abbott Laboratories	
documentation (name and	4551 Great America Parkway	
address)	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:

Barry Simpson

Signature:

Full Name:

Marcy Jaqua

Full Name:

Position:

Regulatory Affairs, Director

Position:

Quality Manager

Date of Approval:

regulatory Arrans, Directo

Date of Approval:

04. Sept. 2015

Place Issued:

Abbott Santa Clara

04 Sep 2015

Date Issued:

SEP 0 4 2015

Effective (Date or Lot

SEP 11 2015

Supersedes:

IRIS V4,

January 10, 2014

Number):

SEP



Certificate Identification: SC-03H80

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
03H80-02	61165	CELL-DYN Ruby, CELL-DYN 3200 Systems CN-FREE HGB/NOC LYSE	Self-declared

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

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Signature:	Barmfores	Signature:	Marcy Squa
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	29. Jun. 2015	Date of Approval:	30 June 2015
Date Issued:	JUN <b>3 0</b> 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V2 January 10, 2014	Effective (Date or Lot Number):	JUL 0 6 2015



Certificate Identification: SC-08H52

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
08H52-01	61165	CELL-DYN Ruby, CELL-DYN 3200 Systems WBC LYSE	Self-declared

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

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Signature:	Barry Spin	Signature:	Marcy Sague
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	29. Jun, 2015	Date of Approval:	30 June 2015
Date Issued:	JUN 3 0 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V2, January 10, 2014	Effective (Date or Lot Number):	JUL 0 6 2015