



Declaration of Conformity



Certificate Identification: SC-99231
 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
99231-01	58237	CELL-DYN 3700 System DILUENT	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>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, January 10, 2014</u>	Effective (Date or Lot Number):	<u>JUL 06 2015</u>

K/T Người đại diện hợp pháp của cơ sở

Ký tên (Ghi họ tên đầy đủ, chức danh)

Xác nhận bằng dấu hoặc chữ ký số



Đinh Thị Hoàng Yến

Phụ trách đăng ký sản phẩm

Bộ phận Chẩn Đoán Y Khoa

CELL-DYN 3700 System
DILUENT
June 2015

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(IRIS V3)
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