

Declaration of Conformity



Certificate Identification: SC-09H46
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
09H46-02	58236	CELL-DYN Emerald CLEANER	Self-declared
09H47-02	61165	CELL-DYN Emerald CN-FREE LYSE	Self-declared
09H48-02	58237	CELL-DYN Emerald 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>02. Dec. 2015</u>	Date of Approval: <u>01 DEC 2015</u>
Date Issued: <u>DEC 03 2015</u>	Place Issued: <u>Abbott Santa Clara</u>
Supersedes: <u>IRIS V6</u> <u>July 6, 2015</u>	Effective (Date or Lot Number): <u>DEC 03 2015</u>

CELL-DYN Emerald Reagents
December 2015

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

Declaration of Conformity
 (IRIS V7)
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