Abbott

# Declaration of Conformity

**Certificate Identification:** SC-09H46

**Legal Manufacturer's Name:** Abbott Laboratories
Diagnostics Division

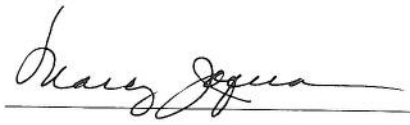
**Legal Manufacturer's Address:** Abbott Park, IL 60064 USA

| 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<br>Max-Planck-Ring-2<br>65205 Wiesbaden, Germany |
| **Storage site of technical documentation (Name and Address)** | Abbott Laboratories<br>4551 Great America Parkway<br>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: | Barry Simpson | Full Name: | Marcy Jaqua |
| Position: | Site Quality Manager | Position: | Director, Regulatory Affairs |
| Date of Approval: | 02-Dec-2015 | Date of Approval: | 01 DEC 2015 |
| Date Issued: | DEC 02 2015 | Place Issued: | Abbott Santa Clara |
| Supersedes: | IRIS V6<br>July 6, 2015 | Effective (Date or Lot Number): | DEC 03 2015 |

Digitally signed by Ceaicovschi Tudor
Date: 2024.11.08 14:37:58 EET
Reason: MoldSign Signature
Location: Moldova