

## Declaration of Conformity

**Certificate Identification:** DOC-08P45-AIDD Longford  
**Legal Manufacturer's Name:** Abbott Ireland Diagnostics Division  
**Legal Manufacturer's Address:** Lisnamuck, Longford, Co. Longford, Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08P4522	60922	Alinity i 25-OH Vitamin D Reagent Kit	Self-declared
08P4532	60922	Alinity i 25-OH Vitamin D Reagent Kit	Self-declared
08P4501	54432	Alinity i 25-OH Vitamin D Calibrators	Self-declared
08P4510	54433	Alinity i 25-OH Vitamin D Controls	Self-declared

<b>Authorized European Representative (name and address)</b>	N/A
<b>Storage site of Technical documentation (name and address)</b>	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland Department: Regulatory Affairs
<b>Harmonized Standards</b>	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: Siobhan Wright

Signature: Lorraine Whitney

Full Name: Siobhan Wright

Full Name: Lorraine Whitney

Position: Director Quality Assurance / Site Quality Head

Position: Senior Manager Regulatory Affairs

Date of Approval: 06 JUN -19

Date of Approval: 05 June 2019

Date Issued: 06 JUN -19

Place Issued: Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland

Supersedes: 17-Dec-2018

Effective (Date or Lot Number): 06 JUN -19