

Declaration of Conformity

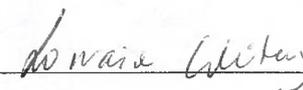
Certificate Identification: DOC-08P45-AIDD Longford
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland

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

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

<p>Signature: <u></u></p> <p>Full Name: <u>Siobhan Wright</u></p> <p>Position: <u>Director Quality Assurance / Site Quality Head</u></p> <p>Date of Approval: <u>06 JUN 19</u></p> <p>Date Issued: <u>06 JUN 19</u></p> <p>Supersedes: <u>17-Dec-2018</u></p>	<p>Signature: <u></u></p> <p>Full Name: <u>Lorraine Whitney</u></p> <p>Position: <u>Senior Manager Regulatory Affairs</u></p> <p>Date of Approval: <u>05 June 2019</u></p> <p>Place Issued: <u>Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland</u></p> <p>Effective (Date or Lot Number): <u>06 JUN 19</u></p>
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