

# Declaration of Conformity

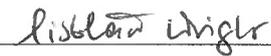
**Certificate Identification:** DOC-07P66-AIDD Longford  
**Legal Manufacturer's Name:** Abbott Ireland Diagnostics Division  
**Legal Manufacturer's Address:** Lisnamuck, Longford, Co. Longford, Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
07P6620	54335	Alinity i Prolactin Reagent Kit	Self-declared
07P6630	54335	Alinity i Prolactin Reagent Kit	Self-declared
07P6601	54337	Alinity i Prolactin Calibrators	Self-declared
07P6610	54338	Alinity i Prolactin 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: <u></u>	Signature: <u></u>
Full Name: <u>Siobhan Wright</u>	Full Name: <u>Lorraine Whitney</u>
Position: <u>Director Quality Assurance/ Site Quality Head</u>	Position: <u>Senior Manager Regulatory Affairs</u>
Date of Approval: <u>24-APR-19</u>	Date of Approval: <u>19 APR 2019</u>
Date Issued: <u>24-APR-19</u>	Place Issued: <u>AIDD Longford</u>
Supersedes: <u>31-DEC-16</u>	Effective (Date or Lot Number): <u>24-APR-19</u>