

## Declaration of Conformity

**Certificate Identification:** DOC-07P92-AIDD Sligo  
**Legal Manufacturer's Name:** Abbott Ireland Diagnostics Division  
**Legal Manufacturer's Address:** Finisklin Business Park, Sligo, Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
07P9220	54665	Alinity i Total PSA Reagent Kit	Annex II List B
07P9230	54665	Alinity i Total PSA Reagent Kit	Annex II List B
07P9201	38208	Alinity i Total PSA Calibrators	Annex II List B
07P9210	38207	Alinity i Total PSA Controls	Annex II List B

<b>Authorized European Representative (name and address)</b>	N/A
<b>Notified Body (name and address)</b>	UL International (UK) Ltd Wonersh House The Guildway Old Portsmouth Road, Guildford, Surrey, GU3 1LR, United Kingdom
<b>Notified Body number</b>	0843
<b>Approval Certificate No.</b>	361
<b>Storage site of technical documentation (name and address)</b>	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, 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 IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: \_\_\_\_\_  
Full Name: \_\_\_\_\_  
Position: \_\_\_\_\_  
Date of Approval: 14 Aug 17  
Date Issued: 14 Aug 17  
Supersedes: Not applicable

Signature: \_\_\_\_\_  
Full Name: \_\_\_\_\_  
Position: \_\_\_\_\_  
Date of Approval: 11 Aug 2017  
Place Issued: AIDD, Sligo  
Effective (Date or Lot Number): 14 Aug 17