

Declaration of Conformity

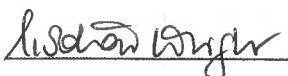
Certificate Identification: 07P50
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
07P5020 07P5030	60979	Alinity i Estradiol Reagent Kit	Self-declared
07P5001	38249	Alinity i Estradiol Calibrators	Self-declared
07P5010	38248	Alinity i Estradiol Controls	Self-declared
07P5040	58208	Alinity i Estradiol Manual Diluent	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.
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: 
Full Name: **Siobhan Wright**
Position: **Director Quality Assurance/
Site Quality Head**

Date of Approval: 07-JAN-2021

Date Issued: 07-JAN-2021

Supersedes 06 June 2019

Signature: 
Full Name: **Lorraine Whitney**
Position: **Director Regulatory Affairs**

Date of Approval: 07 JAN 2021

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

Effective (Lot number or date) 07-JAN-2021