Abbott

Declaration of Conformity

Certificate Identification:	7K62
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
7K62-20 7K62-25 7K62-30 7K62-35	54386	ARCHITECT TSH Reagent Kit	**Self-declared**
7K62-01	38272	ARCHITECT TSH Calibrators	**Self-declared**
7K62-10	38271	ARCHITECT TSH Controls	**Self-declared**

Authorized European Representative (Name and Address)	N/A
Storage of site 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.

Signature: Siobhan Wright

Full Name: **Siobhan Wright**

Position: **Director Quality Assurance/ Site Quality Head**

Date of Approval: 24-APR-19

Date Issued: 24-APR-19

Supersedes: 25-May-2017

Signature: Lorraine Whitney

Full Name: **Lorraine Whitney**

Position: **Senior Manager Regulatory Affairs**

Date of Approval: 19 APR 2019

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

Effective (Date or Lot Number): 24-APR-19