

### 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

<b>Authorized European Representative (Name and Address)</b>	N/A
<b>Storage of site 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: 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