

## Declaration of Conformity

<b>Certificate Identification:</b>	<u>7K63</u>
<b>Legal Manufacturer's Name:</b>	<u>Abbott Ireland Diagnostics Division</u>
<b>Legal Manufacturer's Address:</b>	<u>Lisnamuck, Longford, Co. Longford, Ireland</u>

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K63-20 7K63-25 7K63-30 7K63-35	54417	ARCHITECT Free T <sub>3</sub> Reagent Kit	<b>Self-declared</b>
7K63-01	38261	ARCHITECT Free T <sub>3</sub> Calibrators	<b>Self-declared</b>
7K63-10	54418	ARCHITECT Free T <sub>3</sub> Controls	<b>Self-declared</b>
<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		
<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><i>Siobhan Wright</i></u> Full Name: Siobhan Wright  Position: Director Quality Assurance/ Site Quality Head  Date of Approval: <u>24-APR-19</u>  Date Issued: <u>24-APR-19</u>  Supersedes: <u>09-Jan-2015</u>	Signature: <u><i>Lorraine Whitney</i></u> Full Name: Lorraine Whitney  Position: Senior Manager Regulatory Affairs  Date of Approval: <u>19 APR 2019</u>  Place Issued: Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.  Effective (Date or Lot Number): <u>24-APR-19</u>
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