Abbott

# Declaration of Conformity

**Certificate Identification:** DoC-7K70-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 |
|---|---|---|---|
| 7K70-20 | 54665 | ARCHITECT Total PSA Reagent Kit | **Annex II List B** |
| 7K70-25 | 54665 | ARCHITECT Total PSA Reagent Kit | **Annex II List B** |
| 7K70-30 | 54665 | ARCHITECT Total PSA Reagent Kit | **Annex II List B** |
| 7K70-35 | 54665 | ARCHITECT Total PSA Reagent Kit | **Annex II List B** |
| 7K70-01 | 38208 | ARCHITECT Total PSA Calibrators | **Annex II List B** |
| 7K70-10 | 38207 | ARCHITECT Total PSA Controls | **Annex II List B** |

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|---|---|
| **Authorized European Representative (name and address)** | N/A |
| **Notified Body (name and address)** | TÜV SÜD Product Service GmbH<br>Ridlerstraße 65<br>80339 Munich<br>Germany |
| **Notified Body number** | 0123 |
| **Approval Certificate No.** | V1 0019220008 |
| **Storage site of technical documentation (name and address)** | Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland<br>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 IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.**

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| Signature: | N. WALSH (α) | Signature: | |
| Full Name: | Joe Murray (α) | Full Name: | Noel Haren |
| Position: | Director Quality Assurance/Site Quality Head | Position: | Manager Regulatory Affairs |
| Date of Approval: | 25/11/19 | Date of Approval: | 25 Nov 2019 |
| Date Issued: | 25 Nov 2019 | Place Issued: | AIDD Sligo |
| Supersedes: | 16 October 2019 | Effective (Date or Lot Number): | 25 Nov 2019 |

α Ref attached delegation memo
25/11/2019