Abbott

Declaration of Conformity

Certificate Identification: DOC-09P26-SD-DELK-TPM

Legal Manufacturer's Name: Abbott GmbH

Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09P2625	60779	Alinity i Active-B12 (Holotranscobalamin) Reagent Kit (2x100 tests)	**Self-declared**
09P2635	60779	Alinity i Active-B12 (Holotranscobalamin) Reagent Kit (2x500 tests)	**Self-declared**
09P2611	41338	Alinity i Active-B12 (Holotranscobalamin) Controls	**Self-declared**
09P2602	41337	Alinity i Active-B12 (Holotranscobalamin) Calibrators	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage of technical documentation (name and address)	Axis-Shield Diagnostics Ltd, Luna Place, The Technology Park, Dundee DD2 1XA, United Kingdom
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: J. A

Full Name: **Dr. Jörg Amborn**

Position: **Director Quality Assurance**

Date of Approval: 2020-06-25

Signature: Susanne Ulrich

Full Name: **Susanne Ulrich**

Position: **Senior Manager Regulatory Affairs**

Date of Approval: 25/Jun/2020

Date Issued: 25-Jun-2020

Place Issued: 65205 Wiesbaden, Germany

Supersedes: N/A

Effective (Date or Lot Number): 25-Jun-2020