

Declaration of Conformity

Certificate Identification: 08P04
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
08P0424	53475	Microalbumin	Self-declared
08P0404	53477	Microalbumin Calibrators	Self-declared
08P0414	53478	Microalbumin Controls	Self-declared

Authorized European Representative (name and address)	Not Applicable
Storage of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland And FUJIFILM Wako Pure Chemical Corporation Mie Plant, 2613-2 Oaza, Ogohara, Komono-cho, Mie-gun, Mie, 510-1222, Japan
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: C. Becker
 Full Name (printed): **Claudia Becker**
 Position: **Director Quality Assurance**

Signature: [Signature]
 Full Name (printed): **Thomas Breslin**
 Position: **Manager Regulatory Affairs**

Date of Approval: 05 May 2021

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Date Issued: 05-May-2021

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

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