

## Declaration of Conformity

**Certificate Identification:** DOC-08P4320, 08P4301, 08P4310-SD DLK 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
08P4320	59090	Alinity c Hemoglobin A1c Reagent Kit	Self-declared
08P4301	53315	Alinity c Hemoglobin A1c Calibrators	Self-declared
08P4310	44435	Alinity c Hemoglobin A1c Controls	Self-declared

<b>Authorized European Representative (name and address)</b>	N/A
<b>Storage site of technical documentation (name and address)</b>	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038, USA
<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>C. Becker</u>	Signature: <u>Tiffini Jenkins</u>
Full Name: <b>Claudia Becker</b>	Full Name: <b>Tiffini Jenkins</b>
Position: <b>Director Quality Assurance</b>	Position: <b>Manager Regulatory Affairs</b>
Date of Approval: <u>02 Feb 2022</u>	Date of Approval: <u>1-Feb-2022</u>
	Date Issued: <u>02 Feb 2022</u>
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