



Declaration of Conformity

Certificate Identification:
Legal Manufacturer's Name:

ARCH Sys Acc LC
Abbott Laboratories
Diagnostics Division

IRIS V4

Legal Manufacturer's Address:

Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
4D18-03	56701	ARCHITECT Septum	Self-declared
4D19-01	56701	ARCHITECT Replacement Caps	Self-declared
7C14-01	56676	ARCHITECT Sample Cups	Self-declared
7C15-02	56676	ARCHITECT Reaction Vessels	Self-declared
7C15-03	56676	ARCHITECT Reaction Vessels	Self-declared

Authorized European Representative (Name and Address)	Abbott GmbH & Co. KG Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
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:

Full Name:

Katerina Damjanoska

Position:

Site Quality Director

Date of Approval:

5/29/2019

Date Issued:

22 July 2019

Supersedes:

02 June 2015

Signature:

Full Name:

MaryCaren Muzawski

Position:

Regulatory Affairs Director

Date of Approval:

22 July 19

Place Issued:

Abbott Laboratories, Diagnostics
Division, Abbott Park, IL 60064 USA

Effective (Date or
Lot Number):

22 July 19