ABBOTT

Declaration of Conformity

Certificate Identification: 1G06
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
01G06-11	56676	ARCHITECT c8000 PROCESSING MODULE	Self-declared
02J47-41	56676	ARCHITECT c8000 ADD-ON RETEST SAMPLE HANDLER	Self-declared
02J47-42	56676	ARCHITECT c8000 ADD-ON RETEST SAMPLE HANDLER	Self-Declared
02J47-52	56676	ARCHITECT c8000 STAND ALONE RETEST SAMPLE HANDLER	Self-declared
02J47-56	56676	ARCHITECT c8000 RSH KIT	Self-declared
02J47-75	56676	ARCHITECT c8000/c16000 CARD CAGE AND CABLES	Self-declared
02J47-76	56676	ARCHITECT c8000/c16000 CARD CAGE AND CABLES	Self-declared
09D28-03	56676	ARCHITECT cSYSTEMS ICT MODULE	Self-declared
01G06-12	56676	ARCHITECT c8000 SKINS KIT	Self-declared
07L18-12	56676	ARCHITECT c8000 LAS STANDARD KIT	Self-declared
07L18-13	56676	ARCHITECT c8000 LAS STANDARD KIT	Self-declared
07L20-11	56676	ARCHITECT c8000 LAS UPGRADE KIT	Self-declared
07P38-01	56676	ARCHITECT RSH Extension (Optional)	Self-declared
07P39-01	56676	ARCHITECT RSH Extension Accessory Kit (Optional)	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 1921 Hurd Drive Irving, TX 75038 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, and Directive 2011/65/EU the restriction of the use of certain hazardous substances in electrical and electronic equipment (ROHS).

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-27-2016
Date Issued: 9-27-2016
Supersedes: 09/20/2016

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-27-2016
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-27-2016