ABBOTT

Declaration of Conformity

Certificate Identification: 3M74
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
03M74-02	56701	ARCHITECT i2000SR PROCESSING MODULE	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: Thomas Creel

Full Name: Thomas Creel

Position: Director, Quality Assurance

Date of Approval: 19-Feb-2019

Date Issued: 19-FEB-2019

Supersedes: June 20, 2018

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: 19-FEB-2019

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): 19-FEB-2019

Digitally signed by Ceaicovschi Tudor
Date: 2021.02.08 16:19:43 EET
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