

Declaration of Conformity

Certificate Identification: DoC-03R67-09D28-04-SD DELK
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 Device	Classification
03R67-01 (also 03R6701)	56676	Alinity c PROCESSING MODULE	Self-declared
09D28-04	56676	ICT Module	Self-declared

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Canon Medical Systems Corporation, 1385 Shimoishigami, Otawara-shi, Tochigi 324-8550, 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, 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:

Signature:

Full Name:

Full Name:

Position:

Position:

Date of Approval: 16-Jan-2020

Date of Approval: 17-JAN-2020

Date Issued: 17-JAN-2020

Place Issued: 65205 Wiesbaden, Germany

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Effective (Date or Lot Number): 17-JAN-2020