

# Declaration of Conformity

**Certificate Identification:** DoC-08P9670 08P9770 08P9780 08P9870-SD DELK  
**Legal Manufacturer's Name:** Abbott GmbH & Co. KG  
**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
08P9670	59058	Alinity c-series Detergent A	Self-declared
08P9770	59058	Alinity c-series Detergent B	Self-declared
08P9780	59058	Alinity c-series Detergent B	Self-declared
08P9870	56676 (Water Bath Additive) 59058 (Cleaning Solution)	Alinity c-series Maintenance Solutions	Self-declared

<b>Authorized European Representative (name and address)</b>	N/A
<b>Storage site of technical documentation (name and address)</b>	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue, Charlottetown, Prince Edward Island C1E 2B9, Canada.
<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:** \_\_\_\_\_  
**Full Name:** \_\_\_\_\_  
**Position:** \_\_\_\_\_  
**Date of Approval:** 23-May-2018

**Signature:** \_\_\_\_\_  
**Full Name:** \_\_\_\_\_  
**Position:** \_\_\_\_\_  
**Date of Approval:** 23-MAY-2018  
**Date Issued:** 23-MAY-2018  
**Place Issued:** 65205 Wiesbaden, Germany  
**Supersedes:** 22-MAR-2017  
**Effective (Date or Lot Number):** 23-MAY-2018