

DECLARATION OF CONFORMITY

Manufacturer: Sekisui Diagnostics P.E.I. Inc
70 Watts Avenue Charlottetown
Prince Edward Island
C1E 2B9
Canada

European Representative: Sekisui Diagnostics (UK) Ltd
Liphook Way
Allington
Maidstone
Kent ME16 0LQ

Product: 07P7120 Alinity c Direct LDL Reagent Kit
07P7123 Alinity c Direct LDL Reagent Kit

Classification: General IVD

Conformity Assessment Route: Annex III, self-certified

We hereby declare that the above mentioned products meet the provisions of the Council Directive 98/79EC for in vitro diagnostic medical devices. All supporting documents are held by the manufacturer.

Place of Issue: Allington, UK

Signature:

28 APR 2017

Date

Sekisui Diagnostics (UK) Ltd