

DECLARATION OF CONFORMITY

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

European Representative: MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

Product:

Product Code	Name	GMDN Code
07P7120	Alinity c Direct LDL Reagent Kit	53395

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: Prince Edward Island, Canada

Signature: 
Penny White
Senior Manager Regulatory Affairs
Sekisui Diagnostics PEI Inc.

29-Jun-2021
Date