PRO-LAB DIAGNOSTICS

DECLARATION OF CONFORMITY

Pro-Lab Diagnostics hereby ensures and declares that the product(s) listed below comply with the following requirements:

98/79/EC (1998)	IVD Directive
ISO 13485 (2003)	Medical Device Quality Management System
ISO 14971 (2007)	Application of risk management to medical devices
EN980 (2003)	Graphical symbols for use in the labelling of medical devices

This (these) products do not fall under Annex II list A or B in the Directive 98/79/EC and therefore is eligible for self-declaration of conformity under Annex III.

Product(s) and Product code(s):

Prolex™ Streptococcal Grouping Latex Kit	PL.030
Rabbit Coagulase Plasma	PL.850
Testoxidase™Reagent	PL.390
Spot Indote Reagent	PL.391
AmnioTest™	PL.901
Prolex™ E. Coli 0157 Latex Test Reagent Kit	PL. 070/071
Prolex™ Legionella Pneumophilia Serogroup 1 latex	PL.226
Prolex™ Blue Staph Latex Kits	PL.080/081
Prolex™ Blue Staph Xtra Latex Kits	PL.1080/1081

Signed: _____ Date: 2009 03 17

President

Manufacturer Address
Pro-Lab Diagnostics
20 Mural Street
Richmond Hill, Ontario
Canada L4B 1K3

Authorized Representative
Pro-Lab Diagnostics
7 Westwood Court
Neston, Wirral
Merseyside, UK
CH64 3UJ
Tel:15-1353-1613 Fax: 15-1353: 1614