

DECLARATION OF CONFORMITY

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

98/79/EC

ISO 14971

IVD Directive

ISO 13485 (2003)

Medical Device Quality Management System Application of risk management to medical

devices

EN980 (2003)

Graphical symbols for use in the labeling 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):

Serotyping (E.coli, Salmonella, Shigella etc.)

> Date: <u>29/10/2008</u>

General Manager UK

Manufacturer address:

Pro-Lab Diagnostics Unit 7 Westwood Court Clayhill Industrial Estate Neston Cheshire CH64 3UJ Authorised Representative:

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