



Bio-Rad
Laboratories

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Marnes/RA Dept

DECLARATION OF CONFORMITY

MANUFACTURER : BIO-RAD

ADDRESS : 3, boulevard Raymond Poincaré
92430 Marnes-la-Coquette

PRODUCT(S) NAME(S) : **See annex**

CLASSIFICATION : ☐ ANNEXE II-A
☐ ANNEXE II-B
☐ DEVICE FOR SELF TESTING
☒ OTHER DEVICE

NEW PRODUCT(S) (Notification according to article 10 point 4)

☐ YES ☒ NO

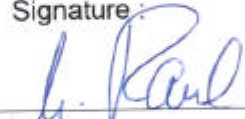
GENERIC DEVICE GROUP CODE (EDMS Nomenclature) :

14 02 03 01 00

GENERIC DEVICE GROUP TERM (EDMS Nomenclature) :

Immunological Identification-Serotyping (*E.coli*, *Salmonella*, *Shigella*, etc.)

We hereby declare that the above mentioned product(s) meet(s) the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* Diagnostic medical devices

Name :	Function :	Date :	Signature :
Kaul, Manuela	Manager, Regulatory Affairs	12/09/03	

ANNEX

Cat#	Products
57201	Antiserum Escherichia coli monovalent O124
57211	Antiserum Escherichia coli monovalent O26
57221	Antiserum Escherichia coli monovalent O55
57231	Antiserum Escherichia coli monovalent O86
57241	Antiserum Escherichia coli monovalent O111
57251	Antiserum Escherichia coli monovalent O119
57261	Antiserum Escherichia coli monovalent O125
57271	Antiserum Escherichia coli monovalent O126
57281	Antiserum Escherichia coli monovalent O127
57291	Antiserum Escherichia coli monovalent O128
57301	Antiserum Escherichia coli monovalent O114
57311	Antiserum Escherichia coli monovalent O142
57331	Antiserum Escherichia coli trivalent I (O111 + O55 + O26)
57341	Antiserum Escherichia coli trivalent II (O86 + O119 + O127)
57351	Antiserum Escherichia coli trivalent III (O125 + O126 + O128)
57361	Antiserum Escherichia coli trivalent IV (O114 + O124+ O142)
57411	Antiserum Escherichia coli nonavalent