



S&A REAGENTS LAB LTD., PART.



EC Declaration of Conformity

Manufacturers Details:

The legal manufacturer of this product (under European IVD Directive 98/79/EC) is:

S&A REAGENTS LAB LTD., PART., 4 Soi Latphrao-wanghin 28, Latphrao-Wanghin Road, Lat Phrao, Bangkok 10230, Thailand
Tel. +66-2538-8622 Fax: +66-2931-6098
Website: https://serotest-thailand.com
Email: info@serotest-thailand.com Email: saplab1990@gmail.com

Product Description:

Name of Device / Product Group:	See Attached Product Schedule
Intended Use:	See Attached Product Schedule
Product Code:	See Attached Product Schedule
Directive 98/79/EC Classification / Conformity Assessment:	Class IVDD, Annex III, Self-Declaration
EC Design Examination Certificate:	Not Applicable — Product Classified as Self Certification
GMDN Code:	See Attached Product Schedule
EDMA Classification:	See Attached Product Schedule
Notified Body:	Not Applicable — Product Classified as Self Certification
Authorised Representative:	Tel. +66-2538-8622 info@serotest-thailand.com

Declaration:

These devices are classified as general in vitro diagnostic medical devices (IVDs) are subject to the European Directive 98/79/EC (IVDD). S&A REAGENTS LAB LTD., PART. declares that the above-mentioned product fulfills the relevant provisions of Directive 98/79/EC concerning in vitro diagnostic medical devices, and that for the above-mentioned product the conformity assessment procedure Annex III has been executed in accordance with the aforementioned Directive. All supporting documentation is retained at the premises of the manufacturer.

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Product Schedule

The following product codes are covered by this EC Declaration of Conformity

Product Group:	See Attached Product Schedule
Intended Use:	See Attached Product Schedule
	See Attached Product Schedule
Product Code(s):	Salmonella Antiserum (various)
EDMA Classification:	14 02 03 01 00 Serotyping (E.coli, Salmonella, Shigella, etc.)
GIVD Classification:	15.01.10.01 Salmonella Antigen Detection

Product Group:	See Attached Product Schedule
Intended Use:	See Attached Product Schedule
	See Attached Product Schedule
Product Code(s):	Shigella Antiserum (various)
EDMA Classification:	14 02 03 01 00 Serotyping (E.coli, Salmonella, Shigella, etc.)
GIVD Classification:	15.04.80.90 Other Viral Antigen/Antibody Detection

Product Group:	See Attached Product Schedule
Intended Use:	See Attached Product Schedule
	See Attached Product Schedule
Product Code(s):	Vibrio Cholerae Antiserum (various)
EDMA Classification:	14 02 03 01 00 Serotyping (E.coli, Salmonella, Shigella, etc.)
GIVD Classification:	15.04.80.90 Other Viral Antigen/Antibody Detection

Authorized signature



(Export Sales Manager: Jano Fair)