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DEKLARACJA ZGODNOŚCI CE

Wydana zgodnie z Dyrektywą Rady 98/79/CE
w sprawie wyrobów medycznych do diagnostyki *in vitro*

My,

SPINREACT S.A.U.,
Carretera Santa Coloma, 7
17176 St. Esteve de Bas
(Girona) Hiszpania

Zaświadczamy, że produkty wymienione poniżej są zaprojektowane i przeznaczone do stosowania w diagnostyce *in vitro* i spełniają wszystkie wymagania określone w załączniku I i załączniku III do Dyrektywy Europejskiej 98/79/WE w sprawie wyrobów medycznych do diagnostyki *in vitro* i są klasyfikowane jako ogólne wyroby IVD (inne).

Wyroby są oznaczone znakiem CE zgodnie z Dyrektywą 98/79/WE Parlamentu Europejskiego w sprawie wyrobów medycznych do diagnostyki *in vitro*, co umożliwia ich sprzedaż w Hiszpanii i innych krajach Unii Europejskiej, bez przeszkód w ich eksporcie, jako OGÓLNE WYROBY IVD (inne).

Podpisano przez: Elisenda Gendra – Dyrektor d/s Technicznych
SPINREACT, S.A.
/podpis nieczytelny, pieczęć firmowa/

Miejsce wystawienia: Sant Esteve de Bas, Girona. Hiszpania
Data wystawienia: 24 Maj 2022r.



Ctra. Santa Coloma, 7.
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EC DECLARATION OF CONFORMITY
According to the Council Directive 98/79/CE
for *in vitro* Diagnostic Medical Devices

We,

SPINREACT S.A.U.,
Carretera Santa Coloma, 7
17176 St. Esteve de Bas
(Girona) SPAIN

Confirm that the following listed products have been designed for "in vitro diagnostic" application and that they comply with all parts of the essential requirements as laid out in Annex I and Annex III of the European Directive 98/79 EC for in vitro Diagnostic Medical Devices and **they are classed as to be General IVD (others).**

They carry CE mark in accordance with Directive 98/79/CE of the European Parliament on in vitro diagnosis medical devices, which enables their marketing in Spain and in the other Countries of the European Union, there being no hindrance to their exportation, as **IVD GENERAL PRODUCTS (others).**

A handwritten signature in blue ink, consisting of a stylized 'E' or 'G' shape with a horizontal line crossing it.



Elisenda Gendra – Technical Director.
SPINREACT, S.A.
Sant Esteve de Bas, Girona. Spain
24th Mayo, 2022

| REFERENCES | SEROLOGY |
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| 1205010C | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS |
| 1205006 | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - KIT 4x100 Tests |
| 1205010 | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - KIT 6x100 Tests |
| 1205008 | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - KIT 8x100 Tests |
| 1200105 | ASO LATEX Slide agglutination. 200 Tests |
| 1200101 | ASO LATEX Slide agglutination 50 Test |
| 1200102 | ASO LATEX Slide agglutination 100 Tests |
| 23103 | ASO LATEX Slide agglutination. Reagent |
| 23107 | ASO LATEX. Slide agglutination. Control (+) |
| 1200901 | ROSA DE BENGALA / ROSE BENGAL. Slide agglutination. 50 Tests. |
| 1205091 | BRUCELLA ABORTUS. Slide agglutination. 100 Tests |
| 1205092 | BRUCELLA ABORTUS. Slide agglutination. 1x50 mL. |
| 1205097 | BRUCELLA MELITENSIS. Slide agglutination. 100 Tests |
| 1205211 | CONTROL NEGATIVO POLIVALENTE/POLYVALENT NEGATIVE CONTROL |
| 1205201 | CONTROL POSITIVO POLIVALENTE/POLYVALENT POSITIVE CONTROL |
| 1200205 | FR LATEX / RF LATEX Slide agglutination 200 Test |
| 1200201 | FR LATEX / RF LATEX Slide agglutination 50 Tests |
| 1200202 | FR LATEX / RF LATEX Slide agglutination 100 Tests |
| 23123 | FR LATEX / RF LATEX Slide agglutination. Reagent |
| 23124 | FR LATEX / RF LATEX Slide agglutination. Control (+) |
| 1200601 | hCG -LATEX. Slide agglutination 50 Tests |
| 1200602 | hCG -LATEX. Slide agglutination 100 Tests |
| 1200800 | MI LATEX / IM LATEX. Slide agglutination 20 Tests |
| 1200801 | MI LATEX / IM LATEX. Slide agglutination 50 Tests |
| 1200305 | PCR LATEX /CRP LATEX Slide agglutination 200 Tests |
| 1200301 | PCR LATEX /CRP LATEX Slide agglutination 50 Tests |
| 1200302 | PCR LATEX /CRP LATEX Slide agglutination 100 Tests |
| 23113 | PCR LATEX /CRP LATEX Slide agglutination. Reagent |
| 23114 | PCR LATEX /CRP LATEX Slide agglutination. Control (+) |
| 1205111 | PROTEUS OX19. 100 Tests |
| 1205112 | PROTEUS OX19.1x50 mL. |
| 1205102 | PROTEUS OX2 .1x50 mL. |
| 1205101 | PROTEUS OX2. 100 Tests |
| 1205121 | PROTEUS OXK . 100 Tests |
| 1205122 | PROTEUS OXK.1x50 mL. |
| 1200401 | RPR CARBON. Slide agglutination 150 Tests |
| 1200402 | RPR CARBON. Slide agglutination 500 Tests |
| 1200411 | RPR CARBON. Slide agglutination 2500 Tests |
| 23132 | RPR CARBON. Slide agglutination. Control (+) |
| 23133 | RPR CARBON. Slide agglutination. Reagent |
| 1205011 | SALMONELLA PARATYPHI AH. 100 Tests |
| 1205012 | SALMONELLA PARATYPHI AH. 1x50 mL. |
| 1205021 | SALMONELLA PARATYPHI AO. 100 Tests |
| 1205022 | SALMONELLA PARATYPHI AO. 1x50 mL. |



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| 1205031 | SALMONELLA PARATYPHI BH . 100 Tests |
| 1205032 | SALMONELLA PARATYPHI BH. 1x50 mL. |
| 1205041 | SALMONELLA PARATYPHI BO . 100 Tests |
| 1205042 | SALMONELLA PARATYPHI BO. 1x50 mL. |
| 1205051 | SALMONELLA PARATYPHI CH . 100 Tests |
| 1205052 | SALMONELLA PARATYPHI CH. 1x50 mL. |
| 1205061 | SALMONELLA PARATYPHI CO. 100 Tests |
| 1205062 | SALMONELLA PARATYPHI CO. 1x50 mL. |
| 1205071 | SALMONELLA TYPHI H. 100 Tests |
| 1205072 | SALMONELLA TYPHI H. 1x50 mL. |
| 1205081 | SALMONELLA TYPHI O . 100 Tests |
| 1205082 | SALMONELLA TYPHI O. 1x50 mL. |
| 1200408 | TPHA 100 Tests |
| 1200405 | VDRL ESTABILIZADO / STABILIZED VRDL. Slide agglutination 1500 Tests |
| 1200406 | VDRL ESTABILIZADO / STABILIZED VRDL. Slide agglutination 250 Tests |
| 1200501 | FR WAALER ROSE / RF WAALER ROSE. Slide agglutination 50 Tests |
| 1200502 | FR WAALER ROSE / RF WAALER ROSE. Slide agglutination 100 Tests |

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| 1205004-A | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - KIT 3x100 Tests |
| 1205006-A | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-AA | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-B | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-C | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-D | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-E | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-F | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-G | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-H | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-I | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-J | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-K | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-L | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-M | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-N | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-O | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-P | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-Q | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-R | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-S | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-T | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-U | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-V | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-W | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-X | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |



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| 1205006-Y | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205006-Z | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 4x100 Tests |
| 1205008-A | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 8x100 Tests |
| 1205008-B | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 8x100 Tests |
| 1205008-C | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 8x100 Tests |
| 1205008-D | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 8x100 Tests |
| 1205008-D1 | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 8x100 Tests |
| 1205008-E | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 8x100 Tests |
| 1205008-F | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 8x100 Tests |
| 1205010-A | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 6x100 Tests |
| 1205010-B | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 6x100 Tests |
| 1205010-B1 | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 6x100 Tests |
| 1205010C | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS |
| 1205010-C | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 6x100 Tests |
| 1205010-D | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 6x100 Tests |
| 1205010-E | ANTIGENOS BACTERIANOS / BACTERIAL ANTIGENS - 6x100 Tests |
| 23153 | hCG LATEX. Slide agglutination. Reagent only. 1x5 mL (100T) |
| 1200411 | RPR CARBON |
| 1202001 | RUBAGEN 100 TEST |
| 1201002 | TOXO LATEX. Slide agglutination. 100 Tests |