Gdańsk, 27.05.2020r.

DECLARATION OF CONFORMITY

Manufacturer: Research and Development Department Of Salmonella Center IMMUNOLAB Ltd.

Poland, 80-822 Gdańsk, Street: Kładki 24

Medical device for in vitro diagnostic: Serum for slide agglutination of Salmonella

<u>Risk qualification</u>: in vitro diagnostic medical device, other than in vitro diagnostic medical device from list A and list B, other than self-testing device and other than device for performance evaluation, in accordance Annex II, list A and B of Directive 98/79/EC

We declare that Serum for slide agglutination of *Salmonella* is in accordance with Directive 98/79/EC of the European Parliament and of the Council on medical devices used for *in vitro* diagnosis.

The conformity assessment procedure complies with Annex III of the Directive 98/79/EC.

The technical documentation referred to at Annex III of the Directive 98/79/EC is located at the manufacturer's premises and is available on request within 5 years of the end of production.

(F

Serum for slide agglutination assay of Salmonella has been marked with the sign:

: 2

Prezes Zarządu mgr Dorota Lieder

.....

(Chairman of the Board)

Annex to the Declaration of Conformity of 27.05.2020

ah

Sera for Salmonella slide agglutination:

LIST

011	HE SHERE
Polyvalent antiserum OM	<u></u>
Ready-to-use rabbit serum, preserved with thimerosal	
Polyvalent antiserum OMA (groups A,B,D ₁ ,D ₂ ,E ₁ ,E ₄)	
Ready-to-use rabbit serum, preserved with thimerosal Polyvalent antiserum OMB (groups C ₁ ,C ₂ ,C ₃ ,F,G,H)	
Polyvalent antiserum OWB (gloups of ozios), yay y	
Ready-to-use rabbit serum, preserved with thimerosal	
Polyvalent antiserum HM	
Deady to use rabbit serum preserved with unnervous	
Polyvalent antiserum HE (eh, enx, enz ₁₅)	
Polyvalent antiserum H2 (gr, gr, gr, gm, gm, gp, gpu, gt, gst, gq) Polyvalent antiserum HG (fg, fgs, gm, gmq, gmt, gp, gpu, gt, gst, gq)	
Polyvalent antiserum HG (19, 195, 911, 911, 911, 917, 917, 917, 917, 917	
Dradu to uso rabbit serum Dreselved with dimoroda.	
Polyvalent antiserum HL (Iv, Iw, Iz ₁₃ , Iz ₂₈)	
Deady to use rabbit serum, preserved with unnerosa	CONTRACTOR OF STREET
Debaselent enticorium H/A (74/23, 44/24)	
Deadu to use rabbit serum preserved with thinkerosa	
D Louisent entierrum H1 (Taciols 1.2.0.0.1)	
Ready-to-use rabbit serum, preserved with minerood	
D-havelent anticorum HO.S.I	
Poody-to-use rabbit serum, preserved with annorodal	State and the state
a matic anticorum OA (Jaciols 2)	
Beady to use rabbit serum, preserved with mineroed	dina aliantesi
a stic anticorum OB (1201015 4.3)	
Deadu to uso rabbit seriim Dreserved with dimerced.	
	100 C
Ready to use rabbit serum, preserved with thinknesser	attraction of the
Deady to use rabbit serum preserved with minerosa	NAME ASSESSED
a setie anticorium (IF (1200) S 0, 10, 10)	Contraction of the second
Deady to use rabbit serum. Dreserved with unmerced.	
a matic anticorum ()FA (Taciois 1.3,13)	THE STREET
Deadu to use rabbit serum, preserved with unnereda	
a the anticorum () (i (12010) \$ 13.22.20)	A DEAD OF THE OWNER
Beady to use rabbit serum, preserved with thinkerosa	
a the antiportim () 2 (((()() (A))	Sector of the later
De adu ta uso rabbit serum. Dreserved with thinterosa	
a matic anticorum () 3 (010005 0L, 0L4)	
Ready-to-use rabbit serum, preserved with third odd	
a the antiporum () 3 10	
Ready-to-use rabbit serum, preserved with uninercour	
a the anticorium () 4	CINES SHE
Ready-to-use rabbit serum, preserved with thinerosal	
a dia antiporum () h	
Ready-to-use rabbit serum, preserved with trimerosal	
a dia anticorum () h (A DATE OF THE
Ready-to-use rabbit serum, preserved with thimerosal	

Somatic antiserum O 7
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 8
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 8.20
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 9
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum Q 10
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 11
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 12
Ready-to-use rabbit serum, preserved with thimerosai
Somatic antiserum O 13 (group OG)
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 13,22
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 13,23
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 14 (group OH)
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 14,24
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 15
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum Q 16
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 18
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 19
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 20
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 21
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum Q 22
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 23
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 28
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 35
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 41
Ready-to-use rabbit serum, preserved with thimerosal
Somatic antiserum O 46
Ready-to-use rabbit serum preserved with this
Ready-to-use rabbit serum, preserved with thimerosal Capsular antiserum Vi
Ready-to-use rabbit serum preserved with this
Ready-to-use rabbit serum, preserved with thimerosal Flagellar antiserum H a
Ready-to-use rabbit serum procented with this
Ready-to-use rabbit serum, preserved with thimerosal Flagellar antiserum H b
Ready-to-use rabbit serum processed with the
Ready-to-use rabbit serum, preserved with thimerosal

Flagellar antiserum H b (concentrated)
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H C
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H d
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H d (concentrated)
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H i
Ready-to-use rabbit serum, preserved with thimerosal
Elagellar antiserum H i (concentrated)
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H g
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H g.m
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H g.p
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H f.g
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H m
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H p
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H f
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H q
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H s
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H t
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H u
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H e,h
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H e,h (concentrated)
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H h
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H e,n,x
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H e,n,x (concentrated)
Ready-to-use rabbit serum, preserved with thimerosal
Floreller entisorum H n
Flagellar antiserum H n Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H X
Flagellar antiserum H x Ready-to-use rabbit serum, preserved with thimerosal
Ready-to-use rabbit serving, proserved minimizers
Flagellar antiserum H k
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H I,v
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H I,v (concentrated)
Ready-to-use rabbit serum, preserved with thimerosal

Flagellar antiserum H v
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H I,w
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H I,w (concentrated)
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H w
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H r
Ready-to-use rabbit serum, preserved with thimerosai
Flagellar antiserum H r (concentrated)
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H y
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H 1,2,5
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H 2
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H 2 (concentrated)
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H 5
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H 5 (concentrated)
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H 6
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H 6 (concentrated)
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H 7
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H z
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H z 6
Ready-to-use rabbit serum processed with this
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H z ₆ (concentrated)
Ready-to-use rabbit serum, preserved with thimerosal Flagellar antiserum H z 10
Ready-to-use rabbit corum preserved a it it it
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H z ₁₀ (concentrated)
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H z 13
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H n,z 15
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H z4 z23
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H z 23
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H z 24
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H z 28
Ready-to-use rabbit serum, preserved with thimerosal
Flagellar antiserum H z 29
Ready-to-use rabbit serum, preserved with thimerosal

 Flagellar antiserum H z 35

 Ready-to-use rabbit serum, preserved with thimerosal

 Flagellar antiserum H z 38

 Ready-to-use rabbit serum, preserved with thimerosal

 Flagellar antiserum H z 39

 Ready-to-use rabbit serum, preserved with thimerosal

 Flagellar antiserum H z 39

 Ready-to-use rabbit serum, preserved with thimerosal

 Flagellar antiserum H z 42

 Ready-to-use rabbit serum, preserved with thimerosal

 Flagellar antiserum H z 53

 Ready-to-use rabbit serum, preserved with thimerosal

Flagellar antiserum H z 57

: *

Ready-to-use rabbit serum, preserved with thimerosal

Company Stamp

Prezes Zanządu mgi Dorota Lieder

Zakład Badawczo-Wdrożeniowy Ośrodka Sałmonella **IMMUNOLAB Sp. z 0.0.** 80-822 Gdańsk ul. Kładki 24 NIP 586 20 11 240 REGON 191818465 www.immunolab.com.pl info@immunolab.com.pl tel/fax 58-781 44 91