

VAT: ES A17027202
Ctra Santa Coloma, 7
E-17176 SANT ESTEVE DE BAS (ESPAÑA)
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spinreact@spinreact.com
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# **Manufacturer's Declaration**

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices, in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body and/or
- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate) and/or
- the compliance of the devices and us, as their manufacturer, with the conditions for the continued placing on the market and putting into service

Manufacturer name	SPINREACT S.A.U.				
Manufacturer address and contact details	Carretera Santa Coloma 7, 17176 Sant Esteve de Bas, Girona, Spain  Phone: +34 972 69 08 00 +34 93 200 35 44				
Single Registration Number (SRN) (if available)	ES-MF-000011023				

Notified body name (if applicable)	
Notified body number (if applicable)	
Directive Certificate number(s) to which this confirmation is made (if applicable)	☐ See attached schedule ☐ Not applicable
Original expiry date as indicated on the Directive Certificate(s) prior to the extension of the validity (if applicable)	☐ See attached schedule ☑ Not applicable
End date of extended validity/transition period	⊠ See attached schedule

We, as the manufacturer declare under our sole responsibility:























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- for the device(s) listed in the attached schedule the conditions for the legal extension of transitional periods as required in Article 110.3b of the IVDR are met and/or
- for the **Directive Certificate(s)** listed in the attached schedule the conditions for the legal extension of validity as required in Article 110.2 of the IVDR are met *and/or*
- the device(s) listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

#### Devices which were self-declared under the IVDD and require notified body involvement under the IVDR

In case of devices for which the conformity assessment procedure pursuant to IVDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to IVDR requires the involvement of a notified body:

Choose one applicable statement:

⊠ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body for the device(s) listed in the attached schedule or its/their substitutes no later than:
□ 26 May 2025 for class D devices
⊠ 26 May 2026 for class C devices
⊠ 27 May 2027 for class B and class A (sterile) devices
☐ Signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR for the device(s) listed in the attached schedule or its/their substitutes no later than:
☐ 26 September 2025 for class D devices
☐ 26 September 2026 for class C devices
$\square$ 27 September 2027 for class B and class A (sterile) devices
☐ We do not intend to lodge an application for conformity for the device as indicated on

- > Directive Certificate(s) as listed above or in the attached schedule
  - Directive Certificate(s) covering the device(s) listed in the attached schedule was/were issued after 25 May 2017, was/were valid on 26 May 2022 and has/have not been withdrawn afterwards.

Choose applicable statements:

the attached schedule.

☐ Original expiry date *before 9 July 2024*:























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	☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII IVDR for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of its/their substitute(s), or
	☐ Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 54(1) IVDR (may be provided upon request), or
	☐ Competent Authority has required us as the manufacturer, in accordance with Article 92(1) IVDR, to carry out the applicable conformity assessment procedure (may be provided upon request)
	Choose one of the following statements only if a derogation per Article 54(1) or a requirement per Article 92(1) has been granted by a Competent Authority:
	☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.
	☐ We do not intend to lodge an application for conformity assessment by 26 May 2025, therefore the transition period will end on 26 May 2025.
	☐ Original expiry date after 9 July 2024:
	Choose one applicable statement:
	☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.
	☐ We do not intend to lodge an application for conformity assessment by 26 May 2025 for the devices as indicated on the attached schedule, therefore the transition period will end on 26 May 2025.
	□ assessment by 26 May 2025, therefore the transition period will end on 26 May 2025.
Qι	uality Management System (QMS)
	Choose one applicable statement:
	☐ QMS in accordance with Article 10(8) IVDR will be put in place by no later than 26 May 2025.
	☐ QMS in accordance with Article 10(8) IVDR is in place.
	☑ Notified body has issued the attached certificate for the IVDR-compliant QMS.























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- > Device(s) listed in the attached schedule (apart from the device indicated to be withdrawn)
  - The device(s) continue(s) to comply with the IVDD.
  - There are no significant changes in the design and intended purpose.
  - The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

#### **SPINREACT S.A.U**

Elisenda Gendra PhD. M.Sc.

QARA manager, PRRC and technical Director

egendra@spinreact.com























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#### **Schedule of Devices**

The above Manufacturer's Declaration is valid for the following devices:

Identification of (e.g., device nan catalogue numb	ne, family/group name device model or	End date of extended validity / transition period	Substitute Device(s) (if applicable)	Directive Certificate number to which this declaration is issued (if applicable)	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the IVDR application was lodged/contract signed (if applicable)
1205010C	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-A	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-AA	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-B	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-C	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197























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Directive Certificate number to which this declaration is issued (if applicable) Original expiry date as indicated on the Directive Certificate prior to the extension of the validity

**Notified Body** name and number that issued the Directive Certificate

(if applicable)

(if applicable)

lodged/contract signed

application was

Notified Body name and

number where the IVDR

					(if applicable)		
1205006-D	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-E	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-F	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-G	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-H	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-I	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-J	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-K	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-L	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-M	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-N	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197























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(if applicable)

					(іт арріісавіе)		
1205006-O	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-P	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-Q	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-R	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-S	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-T	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-U	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-V	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-W	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-X	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006-Y	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197























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(if applicable)

(if applicable)

application was

Notified Body name and

number where the IVDR

lodged/contract signed

(if applicable)

					(ii applicable)		
1205006-Z	ANTIGENOS BACTERIANOS/	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
	BACTERIAL ANTIGENS- 4x100 Tests						, , , ,
1205010-A	ANTIGENOS BACTERIANOS/	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
	BACTERIAL ANTIGENS- 6x100 Tests	01/12/2020	14// (	14// (	14//	14// (	100 Michiana, 0107
1205010-B	ANTIGENOS BACTERIANOS/	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
	BACTERIAL ANTIGENS- 6x100 Tests	31/12/2029	IN/A	IN/A	IN/A	IN/A	TOV Rheimand, 0197
1205010-B1	ANTIGENOS BACTERIANOS/	0.4 /4.0 /0.000	N1/A	N1/A	N1/A	N1/A	Ti'''
	BACTERIAL ANTIGENS- 6x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205010-C	ANTIGENOS BACTERIANOS/	0.4.(4.0.(0.000)	N1/A	N1/A	N1/A	N1/0	Ti''' ( D)
	BACTERIAL ANTIGENS- 6x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205010-D	ANTIGENOS BACTERIANOS/	0.4.(4.0.(0.000)	N1/A	N1/A	N1/A	N1/A	Ti'''   DI
	BACTERIAL ANTIGENS- 6x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205010-E	ANTIGENOS BACTERIANOS/	04/40/0000	NI/A	NI/A	N1/A	N1/A	TÜN/ Dis similarındı. 0407
	BACTERIAL ANTIGENS- 6x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205008-A	ANTIGENOS BACTERIANOS /	0.4.(4.0.(0.000)	N1/A	N1/A	N1/A	N1/A	Ti''' DI : 1 0407
	BACTERIAL ANTIGENS- 8x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205008-B	ANTIGENOS BACTERIANOS/						
	BACTERIAL ANTIGENS - 8x100	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
	Tests						
1205008-C	ANTIGENOS BACTERIANOS/						
	BACTERIAL ANTIGENS - 8x100	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
	Tests						
	T						























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Identification of (e.g., device nan catalogue numb	ne, family/group name device model or	End date of extended validity / transition period	Substitute Device(s) (if applicable)	Directive Certificate number to which this declaration is issued (if applicable)	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the IVDR application was lodged/contract signed (if applicable)
1205008-D	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS - 8x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205008-D1	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS - 8x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205008-E	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS - 8x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205008-F	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS - 8x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205006	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- KIT 4x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205010	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- KIT 6x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205008	ANTIGENOS BACTERIANOS/ BACTERIAL ANTIGENS- KIT 8x100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1200102	ASO LATEX Slide agglutination- 100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197























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(if applicable)

(if applicable)

application was

					(if applicable)		
1200101	ASO LATEX Slide agglutination- 50 Test	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1200105	ASO LATEX Slide agglutination- 200 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
23103	ASO LATEX Slide agglutination- Reagent	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
23107	ASO LATEX. Slide agglutination. Control (+). 1x1 mL	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205091	BRUCELLA ABORTUS. Slide agglutination- 100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205092	BRUCELLA ABORTUS. Slide agglutination. 1x50 mL.	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205097	BRUCELLA MELITENSIS. Slide agglutination- 100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205211	CONTROL NEGATIVO POLIVANENTE/ POLYVALENT NEGATIVE CONTROL	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205201	CONTROL POSITIVO POLIVANENTE/ POLYVALENT POSITIVE CONTROL	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1200202	FR LATEX/ RF LATEX Slide agglutination 100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197























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1200205	FR LATEX/ RF LATEX Slide agglutination 200 Test	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1200201	FR LATEX/ RF LATEX Slide agglutination 50 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
23123	FR LATEX/ RF LATEX Slide agglutination. Reagent	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
23124	RF LATEX. Slide agglutination. Control (+). 1x1 mL	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1200502	FR WAALER ROSE/ RF WAALER ROSE. Slide agglutination 100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1200501	FR WAALER ROSE/ RF WAALER ROSE. Slide agglutination 50 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1200602	hCG-LATEX. Slide agglutination 100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1200601	hCG-LATEX. Slide agglutination 50 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1200800	MI LATEX/ IM LATEX. Slide agglutination 20 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1200801	MI LATEX/ IM LATEX. Slide agglutination 50 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1200302	PCR LATEX/ CRP LATEX Slide agglutination 100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197























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prior to the
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the validity

Notified Body name and number that issued the Directive Certificate

(if applicable)

application was

				(if applicable)	the validity	(if applicable)	
					(if applicable)		
1200305	PCR LATEX/ CRP LATEX Slide agglutination 200 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1200301	PCR LATEX/ CRP LATEX Slide agglutination 50 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
23113	PCR LATEX/ CRP LATEX Slide agglutination. Reagent	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
23114	CRP LATEX. Slide agglutination. Control (+). 1x1 mL	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205111	PROTEUS OX19. 100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205112	PROTEUS OX19.1x50 mL.	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205102	PROTEUS OX2 .1x50 mL.	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205101	PROTEUS OX2. 100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205121	PROTEUS OXK. 100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205122	PROTEUS OXK.1x50 mL.	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1200901	ROSA DE BENGALA/ ROSE BENGAL. Slide agglutination. 50 Tests.	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1200401	RPR CARBON. Slide agglutination 150 Tests	31/12/2028	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1200411	RPR Carbon. Slide agglutination 2500 Tests	31/12/2028	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197























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Notified Body name and

number where the IVDR

lodged/contract signed

Identification of the device(s) <sup>1</sup> (e.g., device name, family/group name device model or catalogue number)

End date of extended validity / transition period

Substitute Device(s) (if applicable)

Directive Certificate number to which this declaration is issued (if applicable)

Original expiry date as indicated on the Directive Certificate prior to the extension of the validity

**Notified Body** name and number that issued the Directive Certificate

(if applicable)

(if applicable)

application was

(if applicable
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					(ii applicable)		
1200402	RPR CARBON. Slide agglutination 500 Tests	31/12/2028	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
23133	RPR CARBON. Slide agglutination. Carbon reagent only. 1x5 mL	31/12/2028	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
23132	RPR CARBON. Slide agglutination. Control (+) 1x1.0 mL	31/12/2028	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205011	SALMONELLA PARATYPHI AH. 100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205012	SALMONELLA PARATYPHI AH. 1x50 mL.	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205021	SALMONELLA PARATYPHI AO. 100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205022	SALMONELLA PARATYPHI AO. 1x50 mL.	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205031	SALMONELLA PARATYPHI BH. 100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205032	SALMONELLA PARATYPHI BH. 1x50 mL.	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205041	SALMONELLA PARATYPHI BO. 100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205042	SALMONELLA PARATYPHI BO. 1x50 mL.	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197























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Identification of the device(s)<sup>1</sup> (e.g., device name, family/group name device model or catalogue number)

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expiry date as
indicated on
the Directive
Certificate
prior to the
extension of
the validity

Notified Body name and number that issued the Directive Certificate

(if applicable)

Notified Body name and number where the IVDR application was lodged/contract signed

(if applicable)

(if applicable)

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1205051	SALMONELLA PARATYPHI CH. 100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205052	SALMONELLA PARATYPHI CH. 1x50 mL.	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205061	SALMONELLA PARATYPHI CO. 100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205062	SALMONELLA PARATYPHI CO. 1x50 mL.	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205071	SALMONELLA TYPHI H. 100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205072	SALMONELLA TYPHI H. 1x50 mL.	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205081	SALMONELLA TYPHI O. 100 Tests	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1205082	SALMONELLA TYPHI O. 1x50 mL.	31/12/2029	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1200408	TPHA 100 Tests	31/12/2028	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1200405	VDRL ESTABILIZADO / STABILIZED VRDL. Slide agglutination 1500 Tests	31/12/2028	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197
1200406	VDRL ESTABILIZADO / STABILIZED VRDL. Slide agglutination 250 Tests	31/12/2028	N/A	N/A	N/A	N/A	TÜV Rheinland; 0197



















