CERTIFICAT UE DE SYSTEME DE GESTION DE LA QUALITE

Règlement (UE) 2017/746, Annexe IX chapitres I et III

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/746, Annex IX chapters I and III

Certificat*/Certificate:* N° 39697 rev. 6

Délivré le */Issued on:* June 2nd, 2026

Certificat délivré à*/Certificate issued to:* **TECHNOGENETICS S.p.A**

Piazza Cinque Giornate, 1

20129 Milano ITALY

SRN: IT-MF-000025331

GMED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) d'audit du système de gestion de la qualité et le(s) rapport(s) d'évaluation de la documentation technique associé(s), le cas échéant, référencé(s) P605580 - P605681 - P605684 - P611336, le système de gestion de la qualité est conforme aux dispositions pertinentes du règlement (UE) 2017/746 pour les produits suivants :

GMED certifies that, on the basis of the results listed in the quality management system audit report(s) and the associated technical documentation assessment report, where appropriate, referenced P605580 - P605681 - P605684 - P611336, the quality management system complies with the relevant provisions of the regulation (EU) 2017/746 for the following products:

Dispositifs destinés à être utilisés pour le dépistage prénatal chez les femmes pour déterminer leur état immunitaire vis-à-vis des agents transmissibles. Dispositifs destinés à être utilisés pour détecter la présence d'un agent infectieux ou l'exposition à un tel agent, y compris les agents sexuellement transmissibles. Dispositifs destinés à être utilisés pour déterminer la charge infectieuse, un état de maladie infectieuse ou un état immunitaire et dispositifs utilisés pour évaluer le stade de la maladie infectieuse. Dispositifs destinés à être utilisés à des fins de dépistage, de détermination ou de contrôle des marqueurs physiologiques pour une maladie spécifique.

Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents. Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents. Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging. Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease.

Voir détails sur addendum / See addendum for additional information

Aux fins de la mise sur le marché de dispositifs de diagnostic in vitro de classe D, de diagnostics compagnons de classe C et de dispositifs de diagnostic in vitro d'autodiagnostic et de diagnostic près du patient de classe B et C, un autre certificat délivré conformément aux dispositions du règlement (UE) 2017/746 est requis. La validité du présent certificat est conditionnée au respect des obligations qui découlent du système de gestion de la qualité approuvé et de la surveillance effectuée par l'organisme notifié prévue par le règlement. Ce certificat est lié par les conditions du contrat.

For the purpose of placing on the market class D in vitro diagnostic devices, class C companion diagnostics and class B and C in vitro diagnostic devices for self-testing and near-patient testing, another certificate issued in accordance with the provisions of Regulation (EU) 2017/746 is required. The validity of this certificate is subject to compliance with the obligations arising from the approved quality management system and the surveillance carried out by the notified body as required by the regulation. This certificate is bound by the conditions of the contract.

Début de validité */Effective date:* June 2nd, 2026 (included)

Valable jusqu'au */Expiry date:* April 17th, 2029 (included)

Signé par :

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On behalf of the President

Béatrice LYS

Technical Director

GMED - 39697 rev. 6

Modifie le certificat 39697-5

1. **Le cas échéant, le nom et l'adresse du mandataire /** *If applicable, the name and address of the authorised representative:*

   Non applicable / *Non applicable*

2. **Identification des sites /** *Identification of sites:*

   - ✓ TECHNOGENETICS S.p.A. - Piazza Cinque Giornate, 1 20129 Milano – ITALY
   - ✓ TECHNOGENETICS S.p.A. - Via della Filanda 24-26, 26900 Lodi – ITALY
   - ✓ TECHNOGENETICS S.p.A. - Localita'Area Industriale ASI SNC, 83040 Morra de Sanctis (AV) – ITALY

3. **Identification des dispositifs /** *Identification of devices:*

Signé par :
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On behalf of the President
Béatrice LYS
Technical Director

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Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • lne-gmed.com

Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*	Référence au certificat requis pour la mise sur le marché du dispositif *Reference to the certificate required for placing on the market the device*
IDS EBV VCA IgG	IS-ID5801	The IDS EBV VCA IgG test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific antibodies of class IgG against Epstein-Barr viral capsid antigen (VCA) in human serum/plasma samples. This assay is used as a diagnostic aid when assessing EBV infections.	B	Non applicable / *Non applicable*

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Technical Director

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IDS EBV VCA IgM	IS-ID5802	The IDS EBV VCA IgM test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific antibodies of class IgM against Epstein-Barr viral capsid antigen (VCA) in human serum/plasma samples. This assay is used as a diagnostic aid when assessing EBV infections.	B	Non applicable / *Non applicable*
IDS EBV EBNA-1 IgG	IS-ID5803	The IDS EBV EBNA-1 IgG test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific antibodies of class IgG against Epstein-Barr nuclear antigen 1 (EBNA-1) in human serum/plasma samples. This assay is used as a diagnostic aid when assessing EBV infections.	B	Non applicable / *Non applicable*
IDS EBV EA IgG	IS-ID5804	The IDS EBV EA IgG test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific antibodies of class IgG against Epstein-Barr virus early antigen-D (EA-D) in human serum/plasma samples. This assay is used as a diagnostic aid when assessing EBV infections.	B	Non applicable / *Non applicable*
IDS EBV Control Set	IS-ID5830	The IDS EBV Control Set consists of human serum matrix at different concentration of EBV antibodies for the quality control of IDS EBV VCA IgG, IDS EBV VCA IgM, IDS EBV EBNA-1 IgG and IDS EBV EA IgG kits.	B	Non applicable / *Non applicable*

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IDS Borrelia IgG	IS-ID6201	The IDS Borrelia IgG test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific antibodies of class IgG against Borrelia burgdorferi sensu lato in human serum/plasma samples. This assay is used as a diagnostic aid when assessing the immune status of the patient with signs and symptoms that are consistent with Lyme disease.	B	Non applicable / *Non applicable*
IDS Borrelia IgM	IS-ID6202	The IDS Borrelia IgM test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific antibodies of class IgM against Borrelia burgdorferi sensu lato in human serum/plasma samples. This assay is used as a diagnostic aid when assessing the immune status of the patient with signs and symptoms that are consistent with Lyme disease.	B	Non applicable / *Non applicable*
IDS Borrelia Control Set	IS-ID6230	The IDS Borrelia Control Set consists of human serum matrix at different concentration of borrelia antibodies for the quality control of the IDS Borrelia IgG and IDS Borrelia IgM kits.	B	Non applicable / *Non applicable*
IDS Measles IgG	IS-ID5901	The IDS Measles IgG test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific antibodies of class IgG against measles virus in human serum/plasma samples. This assay is used as a diagnostic aid when assessing the immune status of the patient related to measles virus infection.	C	Non applicable / *Non applicable*

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IDS Mumps IgG	IS-ID5902	The IDS Mumps IgG test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific antibodies of class IgG against mumps virus in human serum/plasma samples. This assay is used as a diagnostic aid when assessing the immune status of the patient related to mumps virus infection.	C	Non applicable / *Non applicable*
IDS Mumps IgM	IS-ID6002	The IDS Mumps IgM test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific antibodies of class IgM against mumps virus in human serum/plasma samples. This assay is used as a diagnostic aid when assessing the immune status of the patient related to mumps virus infection.	C	Non applicable / *Non applicable*
IDS VZV IgG	IS-ID5903	The IDS VZV IgG test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific antibodies of class IgG against varicella-zoster virus (VZV) in human serum/plasma samples. This assay is used as a diagnostic aid when assessing the immune status of the patient related to varicella-zoster virus infection.	C	Non applicable / *Non applicable*
IDS VZV IgM	IS-ID6003	The IDS VZV IgM test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific antibodies of class IgM against varicella-zoster virus (VZV) in human serum/plasma samples. This assay is used as a diagnostic aid when assessing the immune status of the patient related to varicella-zoster virus infection.	C	Non applicable / *Non applicable*
IDS MMV IgG Control Set	IS-ID5930	The IDS MMV IgG Control Set consists of human serum matrix at different concentration of MMV antibodies for the quality control of the IDS Measles IgG, IDS Mumps IgG and IDS VZV IgG kits.	C	Non applicable / *Non applicable*

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IDS TOXO IgG	IS-ID5001	The IDS TOXO IgG test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with IDS Systems, of specific IgG antibodies directed against Toxoplasma gondii in human serum/plasma samples. This assay is used as a diagnostic aid when assessing immune status of patients related to Toxoplasma gondii infection.	C	Non applicable / *Non applicable*
IDS TOXO IgM	IS-ID5002	The IDS TOXO IgM test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with IDS Systems, of specific IgM antibodies directed against Toxoplasma gondii in human serum/plasma samples. This assay is used as a diagnostic aid when assessing immune status of patients related to Toxoplasma gondii infection.	C	Non applicable / *Non applicable*
IDS TOXO IgG Avidity	IS-ID5101	The IDS TOXO IgG Avidity test is a chemiluminescent immunoassay (CLIA) for the semi-quantitative determination, with IDS Systems, of Avidity Index of specific IgG class antibodies directed against the Toxoplasma gondii in human serum/plasma samples. This assay is used as a diagnostic aid when assessing immune status of patients related to Toxoplasma gondii infection.	C	Non applicable / *Non applicable*
IDS TOXO Control Set	IS-ID5030	The IDS Toxo Control Set consists of human serum matrix at different concentration of Toxoplasma Gondii antibodies used for the quality control of the IDS TOXO IgG and IDS TOXO IgM Kits	C	Non applicable / *Non applicable*
IDS TOXO Avidity Control Set	IS-ID5130	The IDS Toxo Avidity Control Set consists of human serum matrix at different avidity levels of Toxoplasma gondii IgG antibodies for the quality control of the corresponding IDS Toxo IgG Avidity kit.	C	Non applicable / *Non applicable*

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IDS Rubella IgG	IS-ID5201	The IDS Rubella IgG test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific IgG antibodies directed against rubella virus in human serum/plasma samples. This assay is used as a diagnostic aid when assessing immune status of patients related to rubella virus infection.	C	Non applicable / *Non applicable*
IDS Rubella IgM	IS-ID5202	The IDS Rubella IgM test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific IgM antibodies directed against rubella virus in human serum/plasma samples. This assay is used as a diagnostic aid when assessing immune status of patients related to rubella virus infection.	C	Non applicable / *Non applicable*
IDS Rubella Control Set	IS-ID5230	The IDS Rubella Control Set consists of human serum matrix at different concentration of Rubella antibodies for the quality control of the IDS Rubella IgG and IDS Rubella IgM kits.	C	Non applicable / Non applicable
IDS Rubella IgG Avidity	IS-ID5301	The IDS Rubella IgG Avidity test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of Avidity Index of specific IgG class antibodies directed against the rubella virus in human serum/plasma samples. This assay is used as a diagnostic aid when assessing immune status of patients related to rubella virus infection.	C	Non applicable / *Non applicable*
IDS Rubella Avidity Control Set	IS-ID5330	The IDS Rubella Avidity Control Set consists of human serum matrix at different avidity levels of Rubella IgG antibodies for the quality control of the IDS Rubella IgG Avidity kit.	C	Non applicable / *Non applicable*

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IDS CMV IgG	IS-ID5401	The IDS CMV IgG test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific IgG antibodies directed against cytomegalovirus (CMV) in human serum/plasma samples. This assay is used as a diagnostic aid when assessing immune status of patients related to cytomegalovirus (CMV) infection.	C	Non applicable / *Non applicable*
IDS CMV IgM	IS-ID5402	The IDS CMV IgM test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific IgM antibodies directed against cytomegalovirus (CMV) in human serum/plasma samples. This assay is used as a diagnostic aid when assessing immune status of patients related to cytomegalovirus (CMV) infection.	C	Non applicable / *Non applicable*
IDS CMV IgG Avidity	IS-ID5501	The IDS CMV IgG Avidity test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of Avidity Index of specific IgG class antibodies directed against cytomegalovirus in human serum/plasma samples. This assay is used as a diagnostic aid when assessing immune status of patients related to cytomegalovirus (CMV) infection.	C	Non applicable / *Non applicable*
IDS CMV Control Set	IS-ID5430	The IDS CMV Control Set consists of human serum matrix at different concentration of cytomegalovirus antibodies (CMV) for the quality control of the IDS CMV IgG and IDS CMV IgM kits.	C	Non applicable / *Non applicable*
IDS CMV Avidity Control Set	IS-ID5530	The IDS CMV Avidity Control Set consists of human serum matrix at different avidity levels of cytomegalovirus IgG (CMV) antibodies for the quality control of the IDS CMV IgG Avidity kit.	C	Non applicable / *Non applicable*

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IDS HSV 1 IgG	IS-ID5601	The IDS HSV 1 IgG test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific antibodies of class IgG against herpes simplex virus type 1 (HSV 1) in human serum/plasma samples. This assay is used as a diagnostic aid when assessing HSV 1 infections.	C	Non applicable / *Non applicable*
IDS HSV 2 IgG	IS-ID5602	The IDS HSV 2 IgG test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific antibodies of class IgG against herpes simplex virus type 2 (HSV 2) in human serum/plasma samples. This assay is used as a diagnostic aid when assessing HSV 2 infections.	C	Non applicable / *Non applicable*
IDS HSV 1/2 IgM	IS-ID5701	The IDS HSV 1/2 IgM test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific antibodies of class IgM against herpes simplex virus type 1/2 (HSV 1/2) in human serum/plasma samples. This assay is used as a diagnostic aid when assessing HSV 1/2 infections.	C	Non applicable / *Non applicable*
IDS HSV 1/2 IgG Control Set	IS-ID5630	The IDS HSV 1/2 IgG Control Set consists of human serum matrix at different concentration of herpes simplex virus type 1 and type 2 IgG (HSV 1/2 IgG) antibodies for the quality control of IDS HSV IgG kits.	C	Non applicable / *Non applicable*
IDS HSV 1/2 IgM Control Set	IS-ID5730	The IDS HSV 1/2 IgM Control Set consists of human serum matrix at different concentration of herpes simplex virus type 1/2 IgM (HSV 1/2 IgM) antibodies for the quality control of IDS HSV IgM kits.	C	Non applicable / *Non applicable*

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IDS Measles IgM	IS-ID6001	The IDS Measles IgM test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific antibodies of class IgM against measles virus in human serum/plasma samples. This assay is used as a diagnostic aid when assessing the immune status of the patient related to measles virus infection.	C	Non applicable / *Non applicable*
IDS MMV IgM Control Set	IS-ID6030	The IDS MMV IgM Control Set consists of human serum matrix at different concentration of MMV antibodies for the quality control of the IDS Measles IgM, IDS Mumps IgM and IDS VZV IgM kits.	C	Non applicable / *Non applicable*
IDS Parvovirus B19 IgG	IS-ID6301	The IDS Parvovirus B19 IgG test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific antibodies of class IgG against parvovirus B19 in human serum/plasma samples. This assay is used as a diagnostic aid when assessing immune status of patients related to parvovirus B19 infection.	C	Non applicable / *Non applicable*
IDS Parvovirus B19 IgM	IS-ID6302	The IDS Parvovirus B19 IgM test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with IDS Systems, of specific antibodies of class IgM against parvovirus B19 in human serum/plasma samples. This assay is used as a diagnostic aid when assessing immune status of patients related to parvovirus B19 infection.	C	Non applicable / *Non applicable*
IDS Parvovirus B19 Control Set	IS-ID6330	The IDS Parvovirus B19 Control Set consists of human serum matrix at different concentration of parvovirus B19 antibodies for the quality control of IDS Parvovirus B19 IgG and IDS Parvovirus B19 IgM kits.	C	Non applicable / *Non applicable*

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IDS Tetanus IgG	IS-ID6101	The IDS Tetanus IgG test is a chemiluminescent immunoassay (CLIA) for the semi-quantitative determination, with IDS Systems, of specific IgG antibodies directed against tetanus toxin in human serum/plasma samples. This assay is used for the monitoring of the related vaccine therapy.	C	Non applicable / *Non applicable*
IDS Tetanus IgG Control Set	Is-ID6130	The IDS Tetanus IgG Control Set consists of human serum matrix at different concentration of IgG Tetanus antibodies for the quality control of IDS Tetanus IgG kits.	C	Non applicable / *Non applicable*
ZENIT RA Cardiolipin IgG	41424	The ZENIT RA Cardiolipin IgG test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of anti- cardiolipin IgG antibodies in human serum samples. This assay is used as a diagnostic aid in the evaluation of antiphospholipid syndrome (APS).	B	Non applicable / *Non applicable*
ZENIT RA Cardiolipin IgM	41425	The ZENIT RA Cardiolipin IgM test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific anti-cardiolipin IgM antibodies in human serum samples. This assay is used as diagnostic aid in the evaluation of antiphospholipid syndrome (APS).	B	Non applicable / *Non applicable*
ZENIT RA β2-Glycoprotein I IgG	41426	The ZENIT RA β2-Glycoprotein I IgG test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgG antibodies directed against β2-glycoprotein I in human serum samples. This assay is used as diagnostic aid in the evaluation of antiphospholipid syndrome (APS).	B	Non applicable / *Non applicable*

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ZENIT RA β2-Glycoprotein I IgM	41427	The ZENIT RA β2-Glycoprotein I IgM test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgM antibodies directed against β2-glycoprotein I in human serum samples. This assay is used as diagnostic aid in the evaluation of antiphospholipid syndrome (APS).	B	Non applicable / *Non applicable*
ZENIT RA APS IgG CONTROL SET	41450	The ZENIT RA APS IgG Control Set consists of human serum matrix at different concentration of Cardiolipin IgG and β2-Glycoprotein I IgG antibodies for quality control of ZENIT RA Cardiolipin IgG and ZENIT RA β2-Glycoprotein I IgG kits.	B	Non applicable / *Non applicable*
ZENIT RA APS IgM CONTROL SET	41454	The ZENIT RA APS IgM Control Set consists of human serum matrix at different concentration of Cardiolipin IgM and β2-Glycoprotein I IgM antibodies for quality control of ZENIT RA Cardiolipin IgM and ZENIT RA β2-Glycoprotein I IgM kits.	B	Non applicable / *Non applicable*
ZENIT RA Deamidated Gliadin IgA	41420	The ZENIT RA Deamidated Gliadin IgA test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgA antibodies directed against deamidated gliadin peptides (anti-DGP IgA) in human serum samples. This assay is used as diagnostic aid in the evaluation of Celiac Disease (CD).	B	Non applicable / *Non applicable*

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ZENIT RA Deamidated Gliadin IgG	41421	The ZENIT RA Deamidated Gliadin IgG test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgG antibodies directed against deamidated gliadin peptides (anti-DGP IgG) in human serum samples. This assay is used as diagnostic aid in the evaluation of Celiac Disease (CD).	B	Non applicable / *Non applicable*
ZENIT RA t-TG IgA	41422	The ZENIT RA t-TG IgA test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgA antibodies directed against tissue transglutaminase (t-TG) in human serum samples. For samples that do not contain anti-t-TG IgA, the assay is able to suggest a possible IgA deficiency. This assay is used as diagnostic aid in the evaluation of Celiac Disease (CD).	B	Non applicable / *Non applicable*
ZENIT RA t-TG IgG	41423	The ZENIT RA t-TG IgG test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgG antibodies directed against tissue transglutaminase (t-TG) in human serum samples. This assay is used as diagnostic aid in the evaluation of Celiac Disease (CD).	B	Non applicable / *Non applicable*
ZENIT RA Celiac Control Set	41452	The ZENIT RA CELIAC Control Set consists of human serum matrix at different concentration of t-TG IgA, Deamidated Gliadin IgA, and Deamidated Gliadin IgG antibodies for quality control of ZENIT RA t-TG IgA, ZENIT RA Deamidated Gliadin IgA, and ZENIT RA Deamidated Gliadin IgG kits.	B	Non applicable / *Non applicable*

Signé par :
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On behalf of the President
Béatrice LYS
Technical Director

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Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*	Référence au certificat requis pour la mise sur le marché du dispositif *Reference to the certificate required for placing on the market the device*
ZENIT RA t-TG IgG Control Set	41455	The ZENIT RA t-TG IgG Control Set consists of human serum matrix at different concentration of t-TG IgG antibodies for quality control of ZENIT RA t-TG IgG kit.	B	Non applicable / *Non applicable*
ZENIT RA MPO	41428	The ZENIT RA MPO test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgG antibodies directed against myeloperoxidase (MPO) in human serum samples. This assay is used as diagnostic aid in the evaluation of ANCA-associated vasculitis.	B	Non applicable / *Non applicable*
ZENIT RA PR3 enhanced	51328	The ZENIT RA PR3 enhanced test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgG antibodies directed against proteinase 3 (PR3) in human serum samples. This assay is used as diagnostic aid in the evaluation of ANCA-associated vasculitis.	B	Non applicable / *Non applicable*
ZENIT RA GBM	43735	The ZENIT RA GBM test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgG antibodies directed against the Glomerular Basement Membrane (GBM) in human serum samples. This assay is used as diagnostic aid in the evaluation of Goodpasture's syndrome.	B	Non applicable / *Non applicable*

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ZENIT RA ANCA/GBM CONTROL SET	41449	The ZENIT RA ANCA/GBM Control Set consists of human serum matrix at different concentration of myeloperoxidase (MPO), proteinase 3 (PR3), and Glomerular Basement Membrane (GBM) antibodies for quality control of ZENIT RA MPO, ZENIT RA PR3 enhanced, and ZENIT RA GBM kits.	B	Non applicable / *Non applicable*
ZENIT RA CCP	41430	The ZENIT RA CCP test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgG antibodies directed against cyclic citrullinated peptide (CCP) in human serum samples. This assay used as diagnostic aid in the evaluation of rheumatoid arthritis (AR).	B	Non applicable / *Non applicable*
ZENIT RA CCP Control Set	41451	The ZENIT RA CCP Control Set consists of human serum matrix at different concentration of cyclic citrullinated peptide (CCP) IgG antibodies for quality control of ZENIT RA CCP kit.	B	Non applicable / *Non applicable*
ZENIT RA LKM-1	51030	The ZENIT RA LKM-1 (Liver Kidney Microsomes type 1) test is a chemiluminescent immunoassay (CLIA) used for the quantitative determination, with ZENIT RA Systems, of specific IgG class antibodies directed against Liver Kidney Microsomes type 1 (LKM-1) in human serum samples. This assay is used as a diagnostic aid in the evaluation type 2 Autoimmune Hepatitis (AIH).	B	Non applicable / *Non applicable*
ZENIT RA Liver Control Set	46317	The ZENIT RA LIVER Control Set consists of human serum matrix at different concentration of Anti-Mitochondrial Antibodies (M2) and Liver Kidney Microsomes type 1 IgG (LKM-1) antibodies for quality control of ZENIT RA Anti-Mitochondrial Antibodies (M2) and ZENIT RA LKM-1 kits.	B	Non applicable / *Non applicable*

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ZENIT RA Anti-TG	47745	The ZENIT RA Anti-TG (Anti Thyroglobulin Antibodies) test is a chemiluminescent immunoassay (CLIA) used for the quantitative determination, with ZENIT RA Systems, of specific IgG class antibodies acting against human thyroglobulin (Anti-TG), in human serum samples. This assay is used as a diagnostic aid in the evaluation of autoimmune thyroid diseases.	B	Non applicable / *Non applicable*
ZENIT RA Anti-TPO	47746	The ZENIT RA Anti-TPO (Anti Thyroid Peroxidase Antibodies) test is a chemiluminescent immunoassay (CLIA) used for the quantitative determination, with ZENIT RA Systems, of specific IgG class antibodies acting against Thyroid peroxidase (TPO), in human serum samples. This assay is used as a diagnostic aid in the evaluation of autoimmune thyroid diseases.	B	Non applicable / *Non applicable*
ZENIT RA Thyroid Control Set	47760	The ZENIT THYROID Control Set consists of human serum matrix at different concentration of Anti-TPO (Anti Thyroid Peroxidase Antibodies) IgG and Anti-TG (Anti Thyroglobulin Antibodies) IgG antibodies for quality control of ZENIT Anti-TPO and ZENIT RA Anti-TG.	B	Non applicable / *Non applicable*
ZENIT RA ENA SCREEN	41412	The ZENIT RA ENA Screen test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with ZENIT RA Systems, of the specific IgG antibodies directed against SS-A/Ro (60 kDa and 52 kDa), SS-B/La, Sm, U1-snRNP (70 kDa, A and C), Scl-70, and Jo-1 antigens in human serum samples. This assay is used as a diagnostic aid in the evaluation of systemic rheumatic autoimmune diseases.	B	Non applicable / *Non applicable*

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ZENIT RA dsDNA IgG	41413	The ZENIT RA dsDNA IgG test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgG antibodies directed against dsDNA in human serum samples. This assay is used as a diagnostic aid in the evaluation of systemic lupus erythematosus (SLE) diseases.	B	Non applicable / *Non applicable*
ZENIT RA SS-A/Ro	41414	The ZENIT RA SS-A/Ro test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgG antibodies directed against SS-A/Ro in human serum samples. This assay is used as diagnostic aid in the evaluation of systemic lupus erythematosus (SLE) and Sjögren's syndrome (SS) diseases.	B	Non applicable / *Non applicable*
ZENIT RA SS-B/LA	41415	The ZENIT RA SS-B/La test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgG antibodies directed against SS-B/La in human serum samples. This assay is used as diagnostic aid in the evaluation of systemic lupus erythematosus (SLE) and Sjögren's syndrome (SS) diseases.	B	Non applicable / *Non applicable*
ZENIT RA Sm	41416	The ZENIT RA Sm test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgG antibodies directed against the Sm antigens in human serum samples. This assay is used as diagnostic aid in the evaluation of systemic lupus erythematosus (SLE) diseases.	B	Non applicable / *Non applicable*

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ZENIT RA U1-snRNP	41417	The ZENIT RA U1-snRNP test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgG antibodies directed against the U1-snRNP antigens in human serum samples. This assay is used as diagnostic aid in the evaluation of systemic lupus erythematosus (SLE) and mixed connective tissue disease (MCTD) diseases.	B	Non applicable / *Non applicable*
ZENIT RA Scl-70	41418	The ZENIT RA Scl-70 test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, ZENIT RA Systems, of the specific IgG antibodies directed against the DNA topoisomerase I (Scl-70) antigen in human serum samples. This assay is used as diagnostic aid in the evaluation of systemic sclerosis (SSC) diseases.	B	Non applicable / *Non applicable*
ZENIT RA Jo-1	41419	The ZENIT RA Jo-1 test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgG antibodies directed against the histidyl-tRNA synthetase (Jo-1) antigen in human serum samples. This assay is used as diagnostic aid in the evaluation of idiopathic inflammatory myopathies (IIMs) diseases.	B	Non applicable / *Non applicable*
ZENIT RA SS-A/Ro 52 kDA	48265	The ZENIT RA SS-A/Ro 52 kDa test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgG antibodies directed against protein SS-A/Ro 52 kDa in human serum samples. This assay is used as diagnostic aid in the evaluation of systemic lupus erythematosus (SLE), Sjögren's syndrome (SS), systemic sclerosis (SSC) and idiopathic inflammatory myopathies (IIMs) diseases.	B	Non applicable / *Non applicable*

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ZENIT RA SS-A/Ro 60 kDA	48266	The ZENIT RA SS-A/Ro 60 kDa test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgG antibodies directed against protein SS-A/Ro 60 kDa in human serum samples. This assay is used as diagnostic aid in the evaluation of systemic lupus erythematosus (SLE) and Sjögren's syndrome (SS) diseases.	B	Non applicable / *Non applicable*
ZENIT RA ANA Control Set	41448	The ZENIT RA ANA Control Set consists of human serum matrix at different concentration of dsDNA IgG, Centromere B, SS-A/Ro, SS-A/Ro 52 kDa, SS-A/Ro 60 kDa, SS-B/La, Sm,U1-snRNP, Jo-1, and Scl-70 antibodies for quality control of ZENIT RA dsDNA IgG, ZENIT RA Centromere B, ZENIT RA SS-A/Ro, ZENIT RA SS-A/Ro 52 kDa, ZENIT RA SS-A/Ro 60 kDa, ZENIT RA SS-B/La, ZENIT RA Sm, ZENIT RA U1-snRNP, ZENIT RA Jo-1, and ZENIT RA Scl-70 kits.	B	Non applicable / *Non applicable*
ZENIT RA ANA Screen Control Set	41453	The ZENIT RA ANA SCREEN Control Set consists of human serum matrix of different concentration of antinuclear antibodies (ANA) for the quality control of ZENIT RA ANA SCREEN and ZENIT RA ENA SCREEN kits.	B	Non applicable / *Non applicable*
ZENIT RA ANA Screen	41411	The ZENIT RA ANA Screen test is a chemiluminescent immunoassay (CLIA) for the qualitative determination, with ZENIT RA Systems, of the specific IgG antibodies directed against dsDNA, Centromere B, SS-A/Ro (60 kDa and 52 kDa), SS-B/La, Sm, U1-snRNP (70 kDa, A and C), Scl-70, Jo-1 and Rib-P0 antigens in human serum samples. This assay is used as diagnostic aid in the evaluation of systemic rheumatic autoimmune diseases.	B	Non applicable / *Non applicable*

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ZENIT RA Centromere B	41431	The ZENIT RA Centromere B test is a chemiluminescent immunoassay (CLIA) for the quantitative determination, with ZENIT RA Systems, of the specific IgG antibodies directed against Centromere B in human serum samples. This assay is used as diagnostic aid in the evaluation of systemic sclerosis (SSC) diseases.	B	Non applicable / *Non applicable*
ZENIT RA Anti-Mitochondrial Antibodies (M2)	46316	The ZENIT RA Anti-Mitochondrial Antibodies (M2) test is a chemiluminescent immunoassay (CLIA) used for the quantitative determination, with ZENIT RA Systems, of specific IgG class antibodies directed against Anti-Mitochondrial Antibodies (M2) in human serum samples. This assay is used as a diagnostic aid when assessing Primary Biliary Cirrhosis (PBC).	B	Non applicable / *Non applicable*

*mentionnée par le fabricant dans la notice d'utilisation / *as included by the manufacturer in the instructions for use*

4. Historique du certificat / *Certificate history:*

Version du certificat *Version of the certificate*	Date de délivrance *Date of issue*	Modifications apportées *Identification of the changes*
39697 rev. 0	18/04/2024 *04/18/2024*	NA : création / *NA: creation*

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Version du certificat *Version of the certificate*	Date de délivrance *Date of issue*	Modifications apportées *Identification of the changes*
39697 rev. 1	27/06/2024 *06/27/2024*	Reformulation de la destination des dispositifs médicaux / *Rewording of the intended use of the devices* Ajout de références / *Addition of references* ▪ IDS Tetanus IgG (Is-ID6101) ▪ IDS Tetanus IgG Control Set (Is-ID6130)
36697 rev. 2	29/07/2024 *07/29/2024*	Corrections d'erreurs (frappe, destination, doublons) *Error corrections (typing, intended use, duplicates)*

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Référence au certificat précédent *Reference to the previous certificate*	Date de délivrance *Date of issue*	Modifications apportées *Identification of the changes*
36697 rev. 3	09/10/2024 *10/09/2024*	Ajout de références (Projet P605683) / *Addition of references (Project P605683)* ▪ ZENIT RA Cardiolipin IgG - 41424 ▪ ZENIT RA Cardiolipin IgM - 41425 ▪ ZENIT RA β2-Glycoprotein I IgG - 41426 ▪ ZENIT RA β2-Glycoprotein I IgM - 41427 ▪ ZENIT RA APS IgG CONTROL SET - 41450 ▪ ZENIT RA APS IgM CONTROL SET - 41454 ▪ ZENIT RA Deamidated Gliadin IgA - 41420 ▪ ZENIT RA Deamidated Gliadin IgG - 41421 ▪ ZENIT RA t-TG IgA - 41422 ▪ ZENIT RA t-TG IgG - 41423 ▪ ZENIT RA Celiac Control Set - 41452 ▪ ZENIT RA t-TG IgG Control Set - 41455 ▪ ZENIT RA MPO - 41428 ▪ ZENIT RA PR3 enhanced - 51328 ▪ ZENIT RA GBM - 43735 ▪ ZENIT RA ANCA/GBM CONTROL SET - 41449 ▪ ZENIT RA CCP - 41430 ▪ ZENIT RA CCP Control Set - 41451 ▪ ZENIT RA LKM-1 - 51030 ▪ ZENIT RA Liver Control Set - 5103 ▪ ZENIT RA Anti-TG - 46317 ▪ ZENIT RA Anti-TPO - 47746 ▪ ZENIT RA Thyroid Control Set - 47760 ▪ ZENIT RA ENA SCREEN - 41412 ▪ ZENIT RA dsDNA IgG - 41413 ▪ ZENIT RA SS-A/Ro - 41414 ▪ ZENIT RA SS-B/LA - 41415 ▪ ZENIT RA Sm - 41416 ▪ ZENIT RA U1-snRNP - 41417 ▪ ZENIT RA Scl-70 - 41418 ▪ ZENIT RA Jo-1 - 41419 ▪ ZENIT RA SS-A/Ro 52 kDA - 48265 ▪ ZENIT RA SS-A/Ro 60 kDA - 48266 ▪ ZENIT RA ANA Control Set - 41448 ▪ ZENIT RA ANA Screen Control Set - 41453 ▪ ZENIT RA ANA Screen - 41411 ▪ ZENIT RA Centromere B - 41431 ▪ ZENIT RA Anti-Mitochondrial Antibodies (M2) - 46316
36697 rev. 4	15/10/2024 *10/15/2024*	Correction des références commerciales de produits / *Correction of commercial product references* ▪ ZENIT RA LIVER CONTROL SET – 46317 ▪ ZENIT RA Anti-TG - 47745
36697 rev. 5	24/03/2025 *03/24/2025*	Correction de destination / *Correction of intended purpose*
36697 rev. 6	02/06/2026 *06/02/2026*	Mise à jour de l'adresse du fabricant légal / *Update to the legal manufacturer's address*

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5. **Le cas échéant, les informations spécifiques relatives aux conditions ou limitations de la validité du certificat /** *If applicable, specific information relating to the conditions for or limitations to the validity of the certificate :* Non Applicable / *Not applicable*

6. **Le cas échéant, les informations spécifiques relatives à la surveillance effectuée par l'organisme notifié /** *If applicable, specific information about the surveillance carried out by the notified body:* Non Applicable / *Not applicable*

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