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° 38953 rev. 0

Délivré le*/Issued on:* April 14th, 2022

Certificat délivré à*/Certificate issued to:* **PHADIA AB**

Rapsgatan 7P PO. Box 6460

751 37 UPPSALA SWEDEN

SRN: SE-MF-000014170

GMED atteste qu'à l'examen des résultats figurant sur le(s) rapport(s) d'audit du système de gestion de la qualité référencé(s) P602838-P604644, 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 contained in the quality management system audit report(s) referenced P602838-P604644, the quality management system complies with the relevant provisions of the regulation (EU) 2017/746 for the following products:

Dispositifs médicaux de diagnostic in vitro y compris des réactifs, matériaux d'étalonnage et matériaux de contrôle, destinés à être utilisés pour la détermination des marqueurs physiologiques des maladies auto-immunes.

In vitro diagnostic medical devices including reagents, calibrators and control materials, intended to be used for the determination of physiological markers for autoimmune diseases.

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 C (près du patient, autodiagnostic ou diagnostic compagnon) et/ou de classe D, un autre certificat délivré conformément aux dispositions du règlement (UE) 2017/746 est requis.

For the purpose of placing on the market class C in vitro diagnostic devices (devices for self-testing, near patient testing or companion diagnostics) and / or class D, another certificate issued in accordance with the provisions of Regulation (EU) 2017/746 is required.

Début de validité */Effective date:* April 14th, 2022 (included)

Valable jusqu'au */Expiry date:* April 13th, 2027 (included)

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.

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.

GMED DocuSigned by: Béatrice Lys

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

1. **Le cas échéant, le nom et l'adresse du mandataire /** *If applicable, the name and address of the authorised representative:* Non Applicable / *Not Applicable*

2. **Identification des sites /** *Identification of sites:* **Phadia AB - Rapsgatan 7P - P.O. Box 6460, 751 37 Uppsala - SWEDEN**

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

Nom commercial *Commercial name*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
EliA Anti-IgA	EliA Anti-IgA is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to IgA in human serum or plasma (Heparin, Citrate, EDTA) to aid in the diagnosis of Rheumatoid Arthritis. EliA Anti-IgA uses the EliA IgG method on the instruments Phadia 100, Phadia 200 and Phadia 250. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA anti-TG	EliA anti-TG is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to thyroglobulin in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of thyroid diseases such as autoimmune thyroiditis and Graves' disease. EliA anti-TG uses the EliA IgG method on the instruments Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA anti-TPO	EliA anti-TPO is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to thyroid peroxidase in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of thyroid diseases such as autoimmune thyroiditis and Graves' disease. EliA anti-TPO uses the EliA IgG method on the instruments Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA anti-TSH-R	EliA anti-TSH-R is intended for the in vitro quantitative measurement of autoantibodies to the thyroid stimulating hormone receptor (TSH-R) in human serum and plasma (EDTA, Heparin) using a thyroid stimulating monoclonal antibody, as an aid in the clinical diagnosis of Graves' disease (autoimmune hyperthyroidism). EliA anti-TSH-R uses the EliA anti-TSH-R method on the instruments Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA ASCA IgA	EliA ASCA IgA is intended for the in vitro quantitative measurement of immunoglobulin A (IgA) antibodies directed to mannan of Saccharomyces cerevisiae in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of Crohn's disease. EliA ASCA IgA uses the EliA IgA method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B

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EliA ASCA IgG	EliA ASCA IgG is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to mannan of Saccharomyces cerevisiae in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of Crohn's disease. EliA ASCA IgG uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA Calprotectin 2	EliA Calprotectin 2 is intended for the in vitro quantitative measurement of calprotectin in human stool as an aid in the clinical diagnosis of inflammatory bowel diseases. EliA Calprotectin 2 uses the EliA Calprotectin 2 method on the instruments Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA Calprotectin	EliA Calprotectin is intended for the in vitro quantitative measurement of calprotectin in human stool as an aid in the clinical diagnosis of inflammatory bowel diseases. EliA Calprotectin uses the EliA Calprotectin method on the instruments Phadia 100, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA Cardiolipin IgA	EliA Cardiolipin IgA is intended for the in vitro quantitative measurement of immunoglobulin A (IgA) antibodies directed to cardiolipin in serum and plasma (Heparin, Citrate, EDTA) to aid in the diagnosis of antiphospholipid syndrome (APS) and to evaluate the thrombotic risk in patients with systemic lupus erythematosus (SLE). EliA Cardiolipin IgA uses the EliA IgA method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA Cardiolipin IgG	EliA Cardiolipin IgG is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to cardiolipin in serum and plasma (Heparin, Citrate, EDTA) to aid in the diagnosis of antiphospholipid syndrome and to evaluate the thrombotic risk in patients with systemic lupus erythematosus. EliA Cardiolipin IgG uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA Cardiolipin IgM	EliA Cardiolipin IgM is intended for the in vitro quantitative measurement of immunoglobulin M (IgM) antibodies directed to cardiolipin in serum and plasma (Heparin, Citrate, EDTA) to aid in the diagnosis of antiphospholipid syndrome (APS) and to evaluate the thrombotic risk in patients with systemic lupus erythematosus (SLE). EliA Cardiolipin IgM uses the EliA IgM method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B

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EliA CCP IgA	EliA CCP IgA is intended for the in vitro quantitative measurement of immunoglobulin A (IgA) antibodies directed to cyclic citrullinated peptides in human serum and plasma (Heparin, Citrate, EDTA). The presence of anti-cyclic citrullinated peptide IgA antibodies can be used in conjunction with clinical findings and other laboratory tests as an aid in the clinical diagnosis of rheumatoid arthritis. EliA CCP IgA uses the EliA IgA method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA CCP	EliA CCP is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to cyclic citrullinated peptides in human serum and plasma (Heparin, Citrate, EDTA). The presence of anti-cyclic citrullinated peptide antibodies can be used in conjunction with clinical findings and other laboratory tests as an aid in the clinical diagnosis of rheumatoid arthritis . EliA CCP uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA Celikey IgA	EliA Celikey IgA is intended for the in vitro quantitative measurement of immunoglobulin A (IgA) antibodies directed to tissue transglutaminase in human serum and plasma (Citrate, EDTA). EliA Celikey IgA is based on recombinant human tissue transglutaminase as antigen and is useful as an aid in the clinical diagnosis of patients with celiac disease. EliA Celikey IgA uses the EliA IgA method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA Celikey IgG	EliA Celikey IgG is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to tissue transglutaminase in human serum and plasma (Citrate, EDTA). EliA Celikey IgG is based on recombinant human tissue transglutaminase as antigen and is useful as an aid in the clinical diagnosis of patients with celiac disease. EliA Celikey IgG uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA CENP	EliA CENP is intended for the in vitro quantitative measurement of immunoglobulin (IgG) antibodies directed to CENP in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of systemic sclerosis (CREST Syndrome). EliA CENP uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B

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EliA CTD Screen	EliA CTD Screen is intended for the in vitro qualitative measurement of antinuclear immunoglobulin G (IgG) antibodies in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of systemic lupus erythematosus, mixed connective tissue disease, Sjögren's syndrome, scleroderma and polymyositis/dermatomyositis. EliA CTD Screen uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA DFS70	EliA DFS70 is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to DFS70 dense fine speckled 70 kDa (DFS70) in human seruma and plasma (Heparin, Citrate, EDTA) as an aid in the assessment of connective tissue diseases. EliA DFS70 uses the EliA IgG method on the instruments Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA dsDNA	EliA dsDNA is intended for the in vitro quantitative measurement of immunoglobulin (IgG) antibodies directed to dsDNA in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of systemic lupus erythematosus (SLE). EliA dsDNA uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA Fibrillarin	EliA Fibrillarin is intended for the in vitro quantitative measurement of immunoglobulin (IgG) antibodies directed to fibrillarin in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of scleroderma. EliA Fibrillarin uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA GBM	EliA GBM are intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies to α3 chain of collagen IV in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of Goodpasture syndrome and anti-GBM disease. EliA GBM uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA Gliadin^{DP} IgA	EliA Gliadin^{DP} IgA is intended for the in vitro quantitative measurement of immunoglobulin A (IgA) antibodies directed to gliadin in human serum or plasma (Heparin, Citrate, EDTA) to aid in the diagnosis of celiac disease. EliA GliadinDP IgA uses the EliA IgA method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B

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EliA Gliadin^{DP} IgG	EliA Gliadin^{DP} IgG is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to gliadin in human serum or plasma (Heparin, Citrate, EDTA) to aid in the diagnosis of celiac disease. EliA GliadinDP IgG uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA Intrinsic Factor	EliA Intrinsic Factor is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to intrinsic factor in human serum and plasma (Heparin, Citrate, EDTA) to aid in the clinical diagnosis of pernicious anemia. EliA Intrinsic Factor uses the EliA IgG method on the instruments Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA Jo-1	EliA Jo-1 is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to Jo-1 in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of idiopathic inflammatory myopathies. EliA Jo-1 uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA La	EliA La is intended for the in vitro quantitative measurement of immunoglobulin (IgG) antibodies directed to La in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of Sjögren's syndrome and systemic lupus erythematosus. EliA La uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA LKM-1	EliA LKM-1 is intended for the in vitro quantitative measurement of antibodies directed to liver-kidney microsomal antigen, identified as Cytochrome P450 2D6, in human serum and plasma (Heparin, Citrate, EDTA) to aid in the diagnosis of autoimmune hepatitis, type 2. EliA LKM-1 uses the EliA IgG method on the instruments Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA M2	EliA M2 is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to M2 in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of primary biliary cholangitis. EliA M2 uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B

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EliA Mi-2	EliA Mi-2 is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to Mi-2 in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of polymyositis/dermatomyositis. EliA Mi-2 uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA MPO^{S}	EliA MPO^{S} is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to myeloperoxidase in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of microscopic polyangiitis. EliA MPOS uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA Parietal Cell	EliA Parietal Cell is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to parietal cells in human serum and plasma (Heparin, Citrate, EDTA) to aid in the clinical diagnosis of pernicious anemia. EliA Parietal Cell uses the EliA IgG method on the instruments Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA PCNA	EliA PCNA is intended for the in vitro quantitative measurement of immunoglobulin (IgG) antibodies directed to proliferating cell nuclear antigens in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of systemic lupus erythematosus. EliA PCNA uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA PM-Scl	EliA PM-Scl is intended for the invitro quantitative measurement of immunoglobulin (IgG) antibodies directed to polymyositis/scleroderma complex in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of polymyositis/scleroderma overlap syndrome. EliA PM-Scl uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA PR3^{S}	EliA PR3^{S} is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to proteinase 3 in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of Granulomatosis with Polyangiitis (formally called Wegener's Granulomatosis). EliA PR3S uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B

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EliA RF IgA	EliA RF IgA is intended for the in vitro quantitative measurement of immunoglobulin A (IgA) rheumatoid factor in serum and plasma (Heparin, Citrate, EDTA) to aid in the diagnosis of rheumatoid arthritis. EliA RF IgA uses the EliA IgA method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA RF IgG	EliA RF IgG is intended for the in vitro quantitative measurement of immunoglobulin (IgG) rheumatoid factor in serum and plasma (Heparin, Citrate, EDTA) to aid in the diagnosis of rheumatoid arthritis. EliA RF IgG uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA RF IgM	EliA RF IgM is intended for the in vitro quantitative measurement of immunoglobulin M (IgM) rheumatoid factor in serum and plasma (Heparin, Citrate, EDTA) to aid in the diagnosis of rheumatoid arthritis. EliA RF IgM uses the EliA IgM method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA Rib-P	EliA Rib-P is intended for the invitro quantitative measure of immunoglobulin (IgG) antibodies directed to the ribosomal P-Protein in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of systemic lupus erythematosus. EliA Rib-P uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA RNA POL III	EliA RNA Pol III is intended for the in vitro quantitative measurement of immunoglobulin (IgG) antibodies directed to RNA polymerase III in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of systemic sclerosis (diffuse form). EliA RNA Pol III uses the EliA IgG method on the instruments Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA RNP70	EliA RNP70 is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to RNP70 in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of mixed connective tissue disease and systemic lupus erythematosus. EliA RNP70 uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B

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EliA Ro	EliA Ro is intended for the in vitro quantitative measurement of immunoglobulin (IgG) antibodies directed to Ro in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of Sjögren's syndrome and systemic lupus erythematosus. EliA Ro uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA Ro52	EliA Ro52 is intended for the in vitro quantitative measurement of immunoglobulin (IgG) antibodies directed specifically to Ro52 in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of Sjögren's syndrome and systemic lupus erythematosus. EliA Ro52 uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA Ro60	EliA Ro60 is intended for the in vitro quantitative measurement of immunoglobulin (IgG) antibodies directed specifically to Ro60 in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of Sjögren's syndrome and systemic lupus erythematosus. EliA Ro60 uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA Scl-70^{S}	EliA Scl-70^{S} is intended for the in vitro quantitative measurement of immunoglobulin (IgG) antibodies directed to Scl-70 in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of systemic sclerosis (diffuse form). EliA Scl-70S uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA SmD^{P}	EliA SmD^{P} is intended for the in vitro quantitative measurement of immunoglobulin (IgG) antibodies directed to Sm in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of systemic lupus erythematosus. EliA SmDP uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA SmD^{P}-S	EliA SmD^{P}-S is intended for the in vitro quantitative measurement of immunoglobulin (IgG) antibodies directed to Sm in human serum and plasma (Citrate, EDTA) as an aid in the clinical diagnosis of systemic lupus erythematosus. EliA SmDP-S uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B

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EliA ssDNA	EliA ssDNA is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to ssDNA in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of drug induced lupus disease. The test is not definitive in isolation but has to be seen as one parameter in a multicriterion process. EliA ssDNA uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA Symphony	EliA Symphony is intended for the in vitro qualitative measurement of antinuclear immunoglobulin (IgG) antibodies in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of systemic lupus erythematosus, mixed connective tissue disease, Sjögren's syndrome, systemic sclerosis and idiopathic inflammatory myopathies. EliA Symphony uses the EliA IgG method on the instruments Phadia 100, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA Symphony^{S}	EliA Symphony^{S} is intended for the in vitro qualitative measurement of antinuclear immunoglobulin (IgG) antibodies in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of systemic lupus erythematosus, mixed connective tissue disease, Sjögren's syndrome, systemic sclerosis and idiopathic inflammatory myopathies. EliA SymphonyS uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series.	B
EliA U1RNP	EliA U1RNP is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to U1RNP in human serum and plasma (Heparin, Citrate, EDTA) as an aid in the clinical diagnosis of mixed connective tissue disease and systemic lupus erythematosus. EliA U1RNP uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA β2-Glycoprotein I IgA	EliA β2-Glycoprotein I IgA is intended for the in vitro quantitative measurement of immunoglobulin A (IgA) antibodies directed to β2-Glycoprotein I in human serum and plasma (Heparin, Citrate, EDTA) to aid in the diagnosis of antiphospholipid syndrome and to evaluate the thrombotic risk in patients with systemic lupus erythematosus. EliA β2-Glycoprotein I IgA uses the EliA IgA method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B

DocuSigned by:
Beatrice Lys
On behalf of the President
Béatrice LYS
Technical Director

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Nom commercial *Commercial name*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
EliA β2-Glycoprotein I IgG	EliA β2-Glycoprotein I IgG is intended for the in vitro quantitative measurement of immunoglobulin G (IgG) antibodies directed to β2-Glycoprotein I in human serum and plasma (Heparin, Citrate, EDTA) to aid in the diagnosis of antiphospholipid syndrome and to evaluate the thrombotic risk in patients with systemic lupus erythematosus. EliA β2-Glycoprotein I IgG uses the EliA IgG method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B
EliA β2-Glycoprotein I IgM	EliA β2-Glycoprotein I IgM is intended for the in vitro quantitative measurement of immunoglobulin M (IgM) antibodies directed to β2-Glycoprotein I in human serum and plasma (Heparin, Citrate, EDTA) to aid in the diagnosis of antiphospholipid syndrome and to evaluate the thrombotic risk in patients with systemic lupus erythematosus. EliA β2-Glycoprotein I IgM uses the EliA IgM method on the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 2500 and 5000 series. EliA products are to be used in clinical laboratories by trained professionals only.	B

4. Historique du certificat / *Certificate history:*

Référence au certificat précédent *Reference to the previous certificate*	Date de délivrance *Date of issue*	Modifications apportées *Identification of the changes*
Non Applicable / *Not Applicable*	Non Applicable / *Not Applicable*	Non Applicable / *Not Applicable*

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

6. Le cas échéant, les informations spécifiques relatives à la surveillance effectuée dans le cadre du maintien du certificat / *If applicable, specific information relating to the surveillance carried out in the context of maintaining the certificate :* Non Applicable / *Not Applicable*

Digitally signed by: Beatrice Lys

On behalf of the President
Béatrice LYS
Technical Director

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