Autobio Diagnostics Co.,Ltd

No.87 Jingbei Yi Road,National Eco & Tech Development Area Zhengzhou,China,450016
Tel: +86 371 67985313
info@autobio-diagnostics.com
www.autobio-diagnostics.com

Declaration of Conformity

MANUFACTURER:

Autobio Diagnostics Co., Ltd.
No. 87 Jingbei Yi Road
National Eco & Tech Development Area
Zhengzhou
China
450016
SRN: CN-MF-000003348

EUROPEAN REPRESENTATIVE:

QbD RepS BV
Groenenborgerlaan 16
2610 Wilrijk
Belgium
SRN: BE-AR-000000040

PRODUCT:

Please refer to Annex to Declaration of Conformity

NOTIFIED BODY:

TÜV SÜD Product Service GmbH
Located at
Ridlerstr. 65
80339 Munich
Germany

NOTIFIED BODY ID: 0123

We, Autobio Diagnostics Co., Ltd., declare under our sole responsibility that the above IVD medical devices, covered by Annex VIII, meet the provisions of the REGULATION (EU) 2017/746 concerning in vitro diagnostic medical devices, based on the conformity assessment procedure in Annex IX, which apply to them.

We herewith declare that the above mentioned product meets the provisions of the REGULATION (EU) 2017/746 for medical device. All supporting documentations retained under the premises of the manufacture.

The product complies with the general safety and performance requirements in accordance with Annex I of the REGULATION (EU) 2017/746.

EU Quality Management System Certificate No. V12 071134 0017 Rev. 02 by TÜV SÜD

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Product Service GmbH Ridlerstr. 65 80339 Munich Germany.
Valid until: 2026-12-08

OFFICAL ADDRESS:
No. 87 Jingbei Yi Road, National Eco & Tech Development Area Zhengzhou, China, 450016

FACILITY ADDRESS:
No. 87 Jingbei Yi Road, National Eco & Tech Development Area Zhengzhou, China, 450016
No.199, 15th Ave, National Eco&Tech Zone, Zhengzhou, PEOPLE'S REPUBLIC OF CHINA 450016

Issue Place: Zhengzhou

Phone: +86-371-66785303
Email: ra@autobio.com.cn
Name: Guangyu Fu
Position: Vice President

SIGNATURE:_____
DATE: February 10, 2025

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Product Name	REF Number	BASIC UDI-DI	Class	Rule	Intended Purpose
CMV IgG CLIA Microparticles	CMK0701/CMK0702/CMK0703/CMK0704/CMK0705	697015090000105GX	C	Rule 3e	The CMV IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of CMV IgG (specific IgG antibodies to Cytomegalovirus) in human serum or plasma. CMV IgG is used as an aid in the diagnosis of the immune status of an individual, including pre-natal screening of women. It cannot be used for the blood screening.
CMV IgM CLIA Microparticles	CMK0201/CMK0202/CMK0203/CMK0204/CMK0205	697015090000100GM	C	Rule 3e	The CMV IgM CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of CMV IgM (specific IgM antibodies to Cytomegalovirus) in human serum or plasma. CMV IgM is used as an aid in the diagnosis of the immune status of an individual, including pre-natal screening of women. It cannot be used for the blood screening.
Toxo IgG CLIA Microparticles	CMK0601/CMK0602/CMK0603/CMK0604/CMK0605	697015090000104GV	C	Rule 3e	The Toxo IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Toxo IgG (specific IgG antibodies to Toxoplasma gondii) in human serum or plasma. Toxo IgG is used as an aid in the diagnosis of the immune status of an individual, including pre-natal screening of women. It cannot be used for the blood screening.
Toxo IgM CLIA Microparticles	CMK0101/CMK0102/CMK0103/CMK0104/CMK0105	697015090000099HV	C	Rule 3e	The Toxo IgM CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Toxo IgM (IgM antibodies to Toxoplasma gondii) in human serum or plasma. Toxo IgM is used as an aid in the diagnosis of the immune status of an

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					individual, including pre-natal screening of women. It cannot be used for the blood screening.
Rubella IgG CLIA Microparticles	CMK0801/CMK0802/CMK0803/CMK0804/CMK0805	697015090000106GZ	C	Rule 3e	This Rubella IgG CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Rubella IgG (IgG antibodies to rubella virus) in human serum or plasma. Rubella IgG is used as an aid in the diagnosis of the immune status of an individual, including pre-natal screening of women. The device is an automated device and it is for professional laboratory use.
Rubella IgM CLIA Microparticles	CMK0301/CMK0302/CMK0303/CMK0304/CMK0305	697015090000101GP	C	Rule 3e	The Rubella IgM CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Rubella IgM (IgM antibodies to Rubella) in human serum or plasma. Rubella IgM is used as an aid in the diagnosis of the immune status of an individual, including pre-natal screening of women.
CA15-3 CLIA Microparticles	CMB0701 / CMB0702 / CMB0703 / CMB0704/ CMB0705/ CMB0706/ CMB0707/ CMB0708/ CMB0709/ CMB0710	697015090000009H2	C	Rule 3h	The CA15-3 CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of CA15-3 (Carbohydrate Antigen 15-3) in human serum. Clinical determination of CA15-3 is used for dynamic monitoring of patients, which acts as an aid of disease progression or treatment determination of breast cancer.
25-OH Vitamin D CLIA Microparticles	CMS0401/CMS0402/CMS0403/CMS0404/CMS0405/ CMS0406/CMS0407/CMS0408/CMS0409/CMS0410	697015090000075HF	B	Rule 6	The 25-OH Vitamin D CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of 25-OH Vitamin D in human serum or plasma (EDTA, heparin and sodium citrate). This assay is to be used as an aid in the assessment of vitamin D sufficiency.

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Tumor Marker Control II	ZKM0101/ZKM0102/ZKM0201/ZKM0202/ZKM0301/ZKM0302/ZKM0501	697015090000079HP	C	Rule 3h	This product is intended for use as an assayed quality control to monitor the precision of tumor markers, the specified analytes are: AFP, CEA, CA125, CA19-9, CA15-3, CA50, tPSA, fPSA, Ferritin, CA72-4, NSE, SCCA, Cyfra 21-1, CA242, HE4, PGI, PGII, β 2-Microglobulin, β-HCG and TG.
ToRCH IgG Control	ZKA0101/ZKA0201/ZKA0301/ZKA0401/ZKA0102/ZKA0202/ZKA0302/ZKA0402	697015090000358HW	C	Rule 3e	This product is intended for use as an assayed quality control to monitor the precision of ToRCH IgG, the specified analytes are: Toxoplasma gondii IgG, Cytomegalovirus (CMV) IgG, Rubella IgG, Herpes Simples Virus Type 1 (HSV-1) IgG, Herpes Simples Virus Type 2 (HSV-2) IgG.
ToRCH IgM Control	ZKB0101/ZKB0201/ZKB0301/ZKB0401/ZKB0102/ZKB0202/ZKB0302/ZKB0402	697015090000359HY	C	Rule 3e	This product is intended for use as an assayed quality control to monitor the precision of ToRCH IgM, the specified analytes are: Toxoplasma gondii IgM, Cytomegalovirus (CMV) IgM, Rubella IgM, Herpes Simples Virus Type 1 (HSV-1) IgM, Herpes Simples Virus Type 2 (HSV-2) IgM.
Autoimmune Marker Control I	ZKE010101/ZKE010102/ZKE010103/ZKE010104/ZKE010105/ZKE010201/ZKE010202/ZKE010203/ZKE010204/ZKE010205/ZKE010301/ZKE010302/ZKE010303/ZKE010304/ZKE010305	697015090000127H9	B	Rule 6	This product is intended for use as an assayed quality control to monitor the precision of autoimmune marker, the specified analytes are: ANA IgG, Anti-dsDNA IgG, and Anti-CCP IgG.
Thyroid Speciality Control	ZK0501L101/ZK0501L102/ZK0501L103/ZK0501L104/ZK0501L105/ZK0501L106/ZK0501L107/ZK0501L201/ZK0501L202/ZK0501L203/ZK0501L204/ZK0501L205/ZK0501L206/ZK0501L207/ZK0501L	697015090000130GW	B	Rule 6	This product is intended for use as an assayed quality control to monitor the precision of thyroid, the specified analytes are: thyroglobulin antibodies(TgAb), thyroid peroxidase antibody (TPOAb), rT3 and thyrotropin receptor antibody (TRAb).

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Mycoplasma TIES	M0206	697015090000056HB	C	Rule 3 | a	Dehydrated culture medium based assay for the screening, indicative enumeration, identification, typing and antimicrobial susceptibility testing of UP (Ureaplasma parvum), UU (Ureaplasma urealyticum) and MH (Mycoplasma hominis) in human genitourinary tract. This device is intended using on manual.
Mycoplasma IES	M0205	697015090000055H9	C	Rule 3 | a	Dehydrated culture medium based assay for the screening, indicative enumeration, identification and antimicrobial susceptibility testing of UU (Ureaplasma urealyticum and Ureaplasma parvum) and MH (Mycoplasma hominis) in human genitourinary tract.This device is intended using on manual.

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