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BS-IVDR-099

Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 105113 0005 Rev. 02

Manufacturer:

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.23, Jinxiu East Road, Pingshan District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000005655

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12 105113 0005 Rev. 02

Report No.: GZ2313002, GZ2313002-CN

Preceding Certificate No.: V12 105113 0005 Rev. 01

Valid from: 2024-05-24
Valid until: 2025-12-14

Date of Initial Issuance: 2020-12-15

Digitally signed by Bolea Petru
Date: 2025.01.10 18:05:22 EET
Reason: MoldSign Signature
Location: Moldova

Marta Carnielli
Head of Certification IVD

Issue date: 2024-05-24

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EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 105113 0005 Rev. 02

Classification:	Class B
Device Group:	W0101 - CLINICAL CHEMISTRY
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

Classification:	Class B
Device Group:	W0101 - CLINICAL CHEMISTRY
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

Classification:	Class B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

Classification:	Class B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0607 - Devices intended to be used for detection of pregnancy or fertility testing

Classification:	Class B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

Classification:	Class B
Device Group:	W0105 - INFECTIOUS DISEASES
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

Classification:	Class C
Device Group:	W0101 - CLINICAL CHEMISTRY
IVP Code:	IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry
Intended Purpose:	IVR 0301 - Devices intended to be used in screening, diagnosis, staging or monitoring of cancer

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No. V12 105113 0005 Rev. 02

Classification:	Class C
Device Group:	W0101 - CLINICAL CHEMISTRY
IVP Code:	IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

Classification:	Class C
Device Group:	W0101 - CLINICAL CHEMISTRY
IVP Code:	IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

Classification:	Class C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0301 - Devices intended to be used in screening, diagnosis, staging or monitoring of cancer

Classification:	Class C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0401 - Devices intended to be used in screening/confirmation of congenital/inherited disorders

Classification:	Class C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0506 - Other devices intended to be used to determine markers of infections/immune status

Classification:	Class C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

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No. V12 105113 0005 Rev. 02

Classification:	Class C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0606 - Devices intended to be used for non-infectious disease staging

Classification:	Class C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

Classification:	Class C
Device Group:	W0105 - INFECTIOUS DISEASES
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0501 - Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents

Classification:	Class C
Device Group:	W0105 - INFECTIOUS DISEASES
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

Classification:	Class C
Device Group:	W0201010192 - CHEMISTRY ANALYSERS - IVD MEDICAL DEVICE SOFTWARE
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0401 - Devices intended to be used in screening/confirmation of congenital/inherited disorders

The validity of this certificate depends on conditions and/or is limited to the following:	- none -

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Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 105113 0005 Rev. 02

Revision History:

Rev.	Dated	Report	Description
00	2020-12-15	GZ2013005	-
01	2022-09-01	GZ2113002	-
02	2024-05-24	GZ2313002, GZ2313002-CN	Supplemented: Device(s)/group of device(s) added Supplemented: Change to the approved type(s)/device(s)

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Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class D Devices, Class C and B Devices for self-/near-patient testing, Class C Devices Companion Diagnostics)

No. V10 105113 0008 Rev. 01

Manufacturer:

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.23, Jinxiu East Road, Pingshan District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000005655

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s). The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to the applicable Section(s) of Annex IX Chapter II is necessary in addition to this EU Quality Management System Certificate.
All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:V10 105113 0008 Rev. 01

Report No.: GZ2413006

Preceding Certificate No.: V10 105113 0008 Rev. 00

Valid from: 2024-09-23
Valid until: 2025-12-14

Date of Initial Issuance: 2024-05-24

Marta Carnielli
Head of Certification IVD

Issue date: 2024-09-23

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EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class D Devices, Class C and B Devices for self-/near-patient testing, Class C Devices Companion Diagnostics)

No. V10 105113 0008 Rev. 01

Classification:	Class D
Device Group:	W010502 - HEPATITIS VIRUSES (INFECT. IMMUNOLOGY/NAT)
Intended Purpose:	IVR 0502 - Devices intended to be used to detect the presence of, or exposure to transmissible agents in blood, blood components, cells, tissues or organs, or in any of their derivatives, to assess their suitability for transfusion, transplantation or cell administration

Classification:	Class D
Device Group:	W010503 - RETROVIRUSES (INFECT. IMMUNOLOGY/NAT)
Intended Purpose:	IVR 0502 - Devices intended to be used to detect the presence of, or exposure to transmissible agents in blood, blood components, cells, tissues or organs, or in any of their derivatives, to assess their suitability for transfusion, transplantation or cell administration

Classification:	Class D
Device Group:	W010508 - CONTROLS/STANDARDS/CALIBRATORS - (INFECT. IMMUNOLOGY/NAT)
Intended Purpose:	IVR 0502 - Devices intended to be used to detect the presence of, or exposure to transmissible agents in blood, blood components, cells, tissues or organs, or in any of their derivatives, to assess their suitability for transfusion, transplantation or cell administration

The validity of this certificate depends on conditions and/or is limited to the following: - none -

Revision History:

Rev.	Dated	Report	Description
00	2024-05-24	GZ2213004-Q, GZ2213004-Q-CN	Initial issuance
01	2024-09-23	GZ2413006	Supplemented: Device(s)/group of device(s) added

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Product Service

EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX, Chapter II (Class D Devices)

No. V70 105113 0007 Rev. 00

Manufacturer:

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.23, Jinxiu East Road, Pingshan District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000005655

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the Technical Documentation are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX, Chapter II, of this regulation with a positive result. In order to maintain this certificate, the manufacturer shall submit Periodic Safety Update Reports at least annually to the notified body TÜV SÜD Product Service GmbH. Verification of manufactured class D devices according to Annex IX Sections 4.12 and 4.13 is applicable. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX Chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V70 105113 0007 Rev. 00

Report No.: GZ2213004-P1

Valid from: 2024-05-16
Valid until: 2029-05-15

Marta Carnielli
Head of Certification IVD

Issue date: 2024-05-16

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EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX, Chapter II (Class D Devices)

No. V70 105113 0007 Rev. 00

Classification:	Class D
Device Group:	W010502 - HEPATITIS VIRUSES (INFECT. IMMUNOLOGY/NAT)
Basic UDI-DI:	69471455173W7
Intended Purpose:	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of Hepatitis C virus antibody (Anti-HCV) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in diagnosis of HCV infection and for screening of blood donations.
Device(s):	MAGLUMI® Anti-HCV (CLIA) REF: 130210015M, 130610015M, 130710015M

Classification:	Class D
Device Group:	W010508 - CONTROLS/STANDARDS/CALIBRATORS - (INFECT. IMMUNOLOGY/NAT)
Basic UDI-DI:	69471455173W7
Intended Purpose:	The Anti-HCV controls are intended for performing quality control procedures with MAGLUMI Anti-HCV assay when used for the qualitative determination of Anti-HCV in human serum and plasma.
Device(s):	MAGLUMI® Anti-HCV (CLIA) Controls REF: 160201173MT

The validity of this certificate depends on conditions and/or is limited to the following:	- none -

Revision History:

Rev.	Dated	Report	Description
00	2024-05-16	GZ2213004-P1	Initial issuance

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Product Service

EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX, Chapter II (Class D Devices)

No. V70 105113 0009 Rev. 00

Manufacturer:

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.23, Jinxiu East Road, Pingshan District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000005655

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the Technical Documentation are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX, Chapter II, of this regulation with a positive result. In order to maintain this certificate, the manufacturer shall submit Periodic Safety Update Reports at least annually to the notified body TÜV SÜD Product Service GmbH. Verification of manufactured class D devices according to Annex IX Sections 4.12 and 4.13 is applicable. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX Chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V70 105113 0009 Rev. 00

Report No.: GZ2213004-P2

Valid from: 2024-08-15
Valid until: 2029-08-14

Marta Carnielli
Head of Certification IVD

Issue date: 2024-08-15

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EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX, Chapter II (Class D Devices)

No. V70 105113 0009 Rev. 00

Classification:	Class D
Device Group:	W010503 - RETROVIRUSES (INFECT. IMMUNOLOGY/NAT)
Basic UDI-DI:	69471455175WB
Intended Purpose:	The kit is an in vitro chemiluminescence immunoassay for the simultaneously qualitative determination of HIV-1 p24 antigen and antibodies to HIV- 1 (Group M and Group O), HIV-2 in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in diagnosis of HIV-1/HIV-2 infection and for screening of blood donations.
Device(s):	MAGLUMI® HIV Ab/Ag Combi (CLIA) REF: 130219008M, 130619008M, 130719008M

Classification:	Class D
Device Group:	W010508 - CONTROLS/STANDARDS/CALIBRATORS - (INFECT. IMMUNOLOGY/NAT)
Basic UDI-DI:	69471455175WB
Intended Purpose:	The HIV Ab/Ag Combi controls are intended for performing quality control procedures with MAGLUMI HIV Ab/Ag Combi assay when used for the simultaneously qualitative determination of HIV-1 p24 antigen and antibodies to HIV- 1 (Group M and Group O), HIV-2 in human serum and plasma.
Device(s):	MAGLUMI® HIV Ab/Ag Combi (CLIA) Controls REF: 160201175MT

The validity of this certificate depends on conditions and/or is limited to the following:	- none -

Revision History:

Rev.	Dated	Report	Description
00	2024-08-15	GZ2213004-P2	Initial issuance

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