Digitally signed by Bolea Petru
Date: 2023.01.05 14:16:25 EET
Reason: MoldSign Signature
Location: Moldova

CERTIFICATE

DIRECTIVE 98/79/EC
FULL QUALITY ASSURANCE SYSTEM

CeCert Sp. z o.o. hereby confirms that
the quality assurance system in the organization

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No. 23, Jinxiu East Road, Pingshan District, 518122, Shenzhen, P.R. China

with regard to the design, manufacture and final inspection
of in vitro diagnostic medical device referred to in List A in Annex II

The list of devices covered by the scope of this Certificate is included in Annex 1

conforms to the requirements of Annex IV (excluding section 4 and 6)
to Directive 98/79/EC (as amended) implemented into Polish Law,
as evidenced by the audit conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 25.05.2022 – 26.05.2025

Issue date: 25.05.2022

Check it

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device
Certification Department

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

Certificate no: CeCert/134/W/E.1

ANNEX 1

TO THE CERTIFICATE NO. CECERT/134/W/E.1

List of *in vitro* diagnostic medical devices covered by the scope of the Certificate No. CeCert/134/W/E.1:

Device Name	Catalogue Number
MAGLUMI Anti-HBc IgM (CLIA)	130210014M
	130610014M
	130710014M
MAGLUMI Anti-HBc IgM (CLIA) Controls	160201155MT

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device Certification Department

Check it

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

CERTIFICATE

DIRECTIVE 98/79/EC
EC DESIGN-EXAMINATION

CeCert Sp. z o.o. hereby confirms that manufactured by

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No. 23, Jinxiu East Road, Pingshan District, 518122, Shenzhen, P.R. China

in vitro diagnostic medical device referred to in List A in Annex II

The list of devices covered by the scope of this Certificate is included in Annex 1

in term of the design conforms to the requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish Law, as evidenced by the assessment conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 25.05.2022 – 26.05.2025

Issue date: 25.05.2022

Check it

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device Certification Department

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

Certificate no: CeCert/133/W/E.1

ANNEX 1

TO THE CERTIFICATE NO. CECERT/133/W/E.1

List of *in vitro* diagnostic medical devices covered by the scope of the Certificate No. CeCert/133/W/E.1:

Device Name	Catalogue Number
MAGLUMI Anti-HBc IgM (CLIA)	130210014M
	130610014M
	130710014M
MAGLUMI Anti-HBc IgM (CLIA) Controls	160201155MT

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device Certification Department

Check it

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

CERTIFICATE

DIRECTIVE 98/79/EC
FULL QUALITY ASSURANCE SYSTEM

CeCert Sp. z o.o. hereby confirms that
the quality assurance system in the organization

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No. 23, Jinxiu East Road, Pingshan District, 518122, Shenzhen, P.R. China

with regard to the design, manufacture and final inspection
of in vitro diagnostic medical device referred to in List A in Annex II

The list of devices covered by the scope of this Certificate is included in Annex 1

conforms to the requirements of Annex IV (excluding section 4 and 6)
to Directive 98/79/EC (as amended) implemented into Polish Law,
as evidenced by the audit conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 25.05.2022 – 26.05.2025

Issue date: 25.05.2022

Check it

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device
Certification Department

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

Certificate no: CeCert/138/W/E.1

ANNEX 1

TO THE CERTIFICATE NO. CECERT/138/W/E.1

List of *in vitro* diagnostic medical devices covered by the scope of the Certificate No. CeCert/138/W/E.1:

Device Name	Catalogue Number
MAGLUMI Anti-HBc (CLIA)	130210023M
	130610023M
	130710023M
MAGLUMI Anti-HBc (CLIA) Controls	160201453MT

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device Certification Department

Check it

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

CERTIFICATE

DIRECTIVE 98/79/EC
EC DESIGN-EXAMINATION

CeCert Sp. z o.o. hereby confirms that manufactured by

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No. 23, Jinxiu East Road, Pingshan District, 518122, Shenzhen, P.R. China

in vitro diagnostic medical device referred to in List A in Annex II

The list of devices covered by the scope of this Certificate is included in Annex 1

in term of the design conforms to the requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish Law, as evidenced by the assessment conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 25.05.2022 – 26.05.2025

Issue date: 25.05.2022

Check it

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device Certification Department

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

Certificate no: CeCert/137/W/E.1

ANNEX 1

TO THE CERTIFICATE NO. CECERT/137/W/E.1

List of *in vitro* diagnostic medical devices covered by the scope of the Certificate No. CeCert/137/W/E.1:

Device Name	Catalogue Number
MAGLUMI Anti-HBc (CLIA)	130210023M
	130610023M
	130710023M
MAGLUMI Anti-HBc (CLIA) Controls	160201453MT

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device
Certification Department

Check it

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

CERTIFICATE

DIRECTIVE 98/79/EC
FULL QUALITY ASSURANCE SYSTEM

CeCert Sp. z o.o. hereby confirms that
the quality assurance system in the organization

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No. 23, Jinxiu East Road, Pingshan District, 518122, Shenzhen, P.R. China

with regard to the design, manufacture and final inspection
of in vitro diagnostic medical device referred to in List A in Annex II

The list of devices covered by the scope of this Certificate is included in Annex 1

conforms to the requirements of Annex IV (excluding section 4 and 6)
to Directive 98/79/EC (as amended) implemented into Polish Law,
as evidenced by the audit conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 25.05.2022 – 26.05.2025

Issue date: 25.05.2022

Check it

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device
Certification Department

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

Certificate no: CeCert/136/W/E.1

ANNEX 1

TO THE CERTIFICATE NO. CECERT/136/W/E.1

List of *in vitro* diagnostic medical devices covered by the scope of the Certificate No. CeCert/136/W/E.1:

Device Name	Catalogue Number
MAGLUMI Anti-HBe (CLIA)	130210022M
	130610022M
	130710022M
MAGLUMI Anti-HBe (CLIA) Controls	160201452MT

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device Certification Department

Check it

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

CERTIFICATE

DIRECTIVE 98/79/EC
EC DESIGN-EXAMINATION

CeCert Sp. z o.o. hereby confirms that manufactured by

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No. 23, Jinxiu East Road, Pingshan District, 518122, Shenzhen, P.R. China

in vitro diagnostic medical device referred to in List A in Annex II

The list of devices covered by the scope of this Certificate is included in Annex 1

in term of the design conforms to the requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish Law, as evidenced by the assessment conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 25.05.2022 – 26.05.2025

Issue date: 25.05.2022

Check it

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device Certification Department

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

Certificate no: CeCert/135/W/E.1

ANNEX 1

TO THE CERTIFICATE NO. CECERT/135/W/E.1

List of *in vitro* diagnostic medical devices covered by the scope of the Certificate No. CeCert/135/W/E.1:

Device Name	Catalogue Number
MAGLUMI Anti-HBe (CLIA)	130210022M
	130610022M
	130710022M
MAGLUMI Anti-HBe (CLIA) Controls	160201452MT

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device Certification Department

Check it

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

CERTIFICATE

DIRECTIVE 98/79/EC
FULL QUALITY ASSURANCE SYSTEM

CeCert Sp. z o.o. hereby confirms that
the quality assurance system in the organization

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No. 23, Jinxiu East Road, Pingshan District, 518122, Shenzhen, P.R. China

with regard to the design, manufacture and final inspection
of in vitro diagnostic medical device referred to in List A in Annex II

The list of devices covered by the scope of this Certificate is included in Annex 1

conforms to the requirements of Annex IV (excluding section 4 and 6)
to Directive 98/79/EC (as amended) implemented into Polish Law,
as evidenced by the audit conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 25.05.2022 – 26.05.2025

Issue date: 25.05.2022

Check it

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device
Certification Department

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

Certificate no: CeCert/130/W/E.1

ANNEX 1

TO THE CERTIFICATE NO. CECERT/130/W/E.1

List of *in vitro* diagnostic medical devices covered by the scope of the Certificate No. CeCert/130/W/E.1:

Device Name	Catalogue Number
MAGLUMI Anti-HBs (CLIA)	130210010M
	130610010M
	130710010M
MAGLUMI Anti-HBs (CLIA) Controls	160201124MT

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device
Certification Department

Check it

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

CERTIFICATE

DIRECTIVE 98/79/EC
EC DESIGN-EXAMINATION

CeCert Sp. z o.o. hereby confirms that manufactured by

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No. 23, Jinxiu East Road, Pingshan District, 518122, Shenzhen, P.R. China

in vitro diagnostic medical device referred to in List A in Annex II

The list of devices covered by the scope of this Certificate is included in Annex 1

in term of the design conforms to the requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish Law, as evidenced by the assessment conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 25.05.2022 – 26.05.2025

Issue date: 25.05.2022

Check it

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device Certification Department

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

Certificate no: CeCert/129/W/E.1

ANNEX 1

TO THE CERTIFICATE NO. CECERT/129/W/E.1

List of *in vitro* diagnostic medical devices covered by the scope of the Certificate No. CeCert/129/W/E.1:

Device Name	Catalogue Number
MAGLUMI Anti-HBs (CLIA)	130210010M
	130610010M
	130710010M
MAGLUMI Anti-HBs (CLIA) Controls	160201124MT

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device Certification Department

Check it

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ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

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Benannt durch/Designated by
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www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 105113 0002 Rev. 03

Manufacturer:

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

Product Category(ies): **Products for determination of tumor markers (PSA) and infection markers**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V1 105113 0002 Rev. 03

Report no.: GZ2113004

Valid from: 2022-03-29
Valid until: 2024-05-26

Date, 2022-03-29

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Medizinprodukten
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ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 105113 0002 Rev. 03

Model(s):

Total PSA Chemiluminescence immunoassay Kit,
f- PSA Chemiluminescence immunoassay Kit,
Toxo IgG Chemiluminescence immunoassay Kit,
Toxo IgM Chemiluminescence immunoassay Kit,
Rubella IgG Chemiluminescence immunoassay Kit,
Rubella IgM Chemiluminescence immunoassay Kit,
CMV IgG Chemiluminescence immunoassay Kit,
CMV IgM Chemiluminescence immunoassay Kit,
Total PSA (CLIA) Control 1,
Total PSA (CLIA) Control 2,
f-PSA (CLIA) Control 1,
f-PSA (CLIA) Control 2,
Toxo IgG (CLIA) Positive Control,
Toxo IgG (CLIA) Negative Control,
Toxo IgM (CLIA) Positive Control,
Toxo IgM (CLIA) Negative Control,
Rubella IgG (CLIA) Positive Control,
Rubella IgG (CLIA) Negative Control,
Rubella IgM (CLIA) Positive Control,
Rubella IgM (CLIA) Negative Control,
CMV IgG (CLIA) Positive Control,
CMV IgG (CLIA) Negative Control,
CMV IgM (CLIA) Positive Control,
CMV IgM (CLIA) Negative Control,
Anti-HCV (CLIA),
HIV Ab/Ag Combi (CLIA),
Tumor Marker Control,
HBsAg (CLIA)

Facility(ies):

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

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.16, Jinhui Road, Pingshan District, 518122 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

.

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CERTIFICATE

DIRECTIVE 98/79/EC
FULL QUALITY ASSURANCE SYSTEM

CeCert Sp. z o.o. hereby confirms that
the quality assurance system in the organization

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No. 23, Jinxiu East Road, Pingshan District, 518122, Shenzhen, P.R. China

with regard to the design, manufacture and final inspection
of in vitro diagnostic medical device referred to in List A in Annex II

The list of devices covered by the scope of this Certificate is included in Annex 1

conforms to the requirements of Annex IV (excluding section 4 and 6)
to Directive 98/79/EC (as amended) implemented into Polish Law,
as evidenced by the audit conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 25.05.2022 – 26.05.2025

Issue date: 25.05.2022

Check it

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device
Certification Department

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

Certificate no: CeCert/132/W/E.1

ANNEX 1

TO THE CERTIFICATE NO. CECERT/132/W/E.1

List of *in vitro* diagnostic medical devices covered by the scope of the Certificate No. CeCert/132/W/E.1:

Device Name	Catalogue Number
MAGLUMI HBeAg (CLIA)	130210011M
	130610011M
	130710011M
MAGLUMI HBeAg (CLIA) Controls	160201136MT

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device
Certification Department

Check it

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

CERTIFICATE

DIRECTIVE 98/79/EC
EC DESIGN-EXAMINATION

CeCert Sp. z o.o. hereby confirms that manufactured by

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No. 23, Jinxiu East Road, Pingshan District, 518122, Shenzhen, P.R. China

in vitro diagnostic medical device referred to in List A in Annex II

The list of devices covered by the scope of this Certificate is included in Annex 1

in term of the design conforms to the requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish Law, as evidenced by the assessment conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 25.05.2022 – 26.05.2025

Issue date: 25.05.2022

Check it

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device Certification Department

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

Certificate no: CeCert/131/W/E.1

ANNEX 1

TO THE CERTIFICATE NO. CECERT/131/W/E.1

List of *in vitro* diagnostic medical devices covered by the scope of the Certificate No. CeCert/131/W/E.1:

Device Name	Catalogue Number
MAGLUMI HBeAg (CLIA)	130210011M
	130610011M
	130710011M
MAGLUMI HBeAg (CLIA) Controls	160201136MT

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device Certification Department

Check it

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ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

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www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 105113 0006 Rev. 00

Manufacturer:

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

Product:

Screening test for Hepatitis B marker
for Professional Use only

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V7 105113 0006 Rev. 00

Report No.: 713210558

Valid from: 2022-03-11
Valid until: 2025-05-26

Date, 2022-03-11

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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bei Arzneimitteln und
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www.zlg.de
ZLG-BS-245.10.07

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 105113 0006 Rev. 00

Model(s): **MAGLUMI® HBsAg (CLIA)**

Facility(ies):

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

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.16, Jinhui Road, Pingshan District, 518122 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

Parameters:

Id-n°:	Product-Name:	Packaging Size:
130210009M	MAGLUMI® HBsAg (CLIA)	100 Tests/kit
130610009M	MAGLUMI® HBsAg (CLIA)	50 Tests /kit

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ZLG-BS-245.10.07

Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 105113 0004 Rev. 00

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

Product: **Screening test for HIV-1/-2 marker**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V7 105113 0004 Rev. 00

Report No.: 713164232

Valid from: 2021-02-04
Valid until: 2024-05-26

Date, 2021-02-04

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 105113 0004 Rev. 00

Model(s): **MAGLUMI™ HIV Ab/Ag Combi (CLIA)**

Facility(ies):

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

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.16, Jinhui Road, Pingshan District, 518122 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Parameters:

Product-Name:	Catalog No.:	Size:
MAGLUMI™ HIV Ab/Ag Combi (CLIA)	130219008M	100 tests / kit
	130619008M	50 tests / kit

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www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 105113 0002 Rev. 03

Manufacturer:

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

Product Category(ies): **Products for determination of tumor markers (PSA) and infection markers**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V1 105113 0002 Rev. 03

Report no.: GZ2113004

Valid from: 2022-03-29
Valid until: 2024-05-26

Date, 2022-03-29

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

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Model(s):

Total PSA Chemiluminescence immunoassay Kit,
f- PSA Chemiluminescence immunoassay Kit,
Toxo IgG Chemiluminescence immunoassay Kit,
Toxo IgM Chemiluminescence immunoassay Kit,
Rubella IgG Chemiluminescence immunoassay Kit,
Rubella IgM Chemiluminescence immunoassay Kit,
CMV IgG Chemiluminescence immunoassay Kit,
CMV IgM Chemiluminescence immunoassay Kit,
Total PSA (CLIA) Control 1,
Total PSA (CLIA) Control 2,
f-PSA (CLIA) Control 1,
f-PSA (CLIA) Control 2,
Toxo IgG (CLIA) Positive Control,
Toxo IgG (CLIA) Negative Control,
Toxo IgM (CLIA) Positive Control,
Toxo IgM (CLIA) Negative Control,
Rubella IgG (CLIA) Positive Control,
Rubella IgG (CLIA) Negative Control,
Rubella IgM (CLIA) Positive Control,
Rubella IgM (CLIA) Negative Control,
CMV IgG (CLIA) Positive Control,
CMV IgG (CLIA) Negative Control,
CMV IgM (CLIA) Positive Control,
CMV IgM (CLIA) Negative Control,
Anti-HCV (CLIA),
HIV Ab/Ag Combi (CLIA),
Tumor Marker Control,
HBsAg (CLIA)

Facility(ies):

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

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.16, Jinhui Road, Pingshan District, 518122 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

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