

## Declaration of Conformity

**Manufacturer:**

Shenzhen New Industries Biomedical Engineering Co., Ltd.  
No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China  
Tel: +86-755-21536601 Fax: +86-755-28292740

**European Representative:**

Shanghai International Holding Corp. GmbH (Europe)  
Address: Eiffestrasse 80, 20537 Hamburg, Germany  
Tel: +49-40-2513175 Fax: +49-40-255726

**Notified Body:**

TüV SüD Product Service GmbH  
Zertifizierstelle Ridlerstraße 65- 80339 München Germany  
Identification Number: 0123

**EC Certificate No.:** V7 105113 0006 Rev.00; V1 105113 0002 Rev.03

**Product Name:**

MAGLUMI<sup>®</sup> HBsAg (CLIA) 130210009M (100 Tests/kit), 130610009M (50 Tests/kit)

**Intended Use**

The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of HBsAg in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used as an aid in the diagnosis of HBV infection and for screening of blood donations.

**Classification:**

List A (IVDD 98/79/EC, Annex II)

**Conformity Assessment Route:** Annex IV (IVDD 98/79/EC)

We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive:**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

**Standards Applied:**

EN 13612:2002	EN ISO 13485:2016	EN ISO 15223-1:2016	EN ISO 18113-1:2011
EN ISO 23640:2015	EN ISO 14971:2012	EN 13641:2002	EN ISO 18113-2:2011
EN ISO 17511:2003			

**First Start of CE-MARK:** April 13, 2022

**Valid Period:** as the valid period of EC certificate above

**Signature:** Managing Director



**Place, Date of Issue:** Shenzhen, April 14, 2022

## Declaration of Conformity

**Manufacturer:**

Shenzhen New Industries Biomedical Engineering Co., Ltd.  
No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China  
Tel: +86-755-21536601 Fax: +86-755-28292740

**European Representative:**

Shanghai International Holding Corp. GmbH (Europe)  
Address: Eiffestrasse 80, 20537 Hamburg, Germany  
Tel: +49-40-2513175 Fax: +49-40-255726

**Notified Body:**

CeCert Sp. z o.o.  
Address: ul. Żurawia 32/34 lok.49 Warszawa, Poland  
Identification Number: 2934

**EC Certificate No.:** CeCert/129/W/E.1, CeCert/130/W/E.1

**Validity Period:** 25.05.2022 – 26.05.2025

**Product Name:**

MAGLUMI<sup>®</sup> Anti-HBs (CLIA) Controls 160201124MT

**Classification:**

List A (IVDD 98/79/EC, Annex II)

**Conformity Assessment Route:** Annex IV (IVDD 98/79/EC)

We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on *in vitro* diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive:**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

**Standards Applied:**

EN 13612:2002	EN ISO 13485:2016	EN ISO 15223-1:2016	EN ISO 18113-1:2011
EN ISO 23640:2015	EN ISO 14971:2012	EN 13641:2002	EN ISO 18113-2:2011
EN ISO 17511:2003			

**First Start of CE-MARK:** May 26, 2022

**Signature:** General Director



**Place, Date of Issue:** Shenzhen, May 26, 2022





## Declaration of Conformity

**Manufacturer:**

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

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Tel: +49-40-2513175 Fax: +49-40-255726

**Notified Body:**

CeCert Sp. z o.o.  
Address: ul. Żurawia 32/34 lok.49 Warszawa, Poland  
Identification Number: 2934

**EC Certificate No.:** CeCert/129/W/E.1, CeCert/130/W/E.1

**Validity Period:** 25.05.2022 – 26.05.2025

**Product Name:**

MAGLUMI<sup>®</sup> Anti-HBs (CLIA) 130210010M (100 Tests/kit), 130610010M (50 Tests/kit),  
130710010M (30 Tests/kit)

**Classification:**

List A (IVDD 98/79/EC, Annex II)

**Conformity Assessment Route:** Annex IV (IVDD 98/79/EC)

We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive:**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

**Standards Applied:**

EN 13612:2002	EN ISO 13485:2016	EN ISO 15223-1:2016	EN ISO 18113-1:2011
EN ISO 23640:2015	EN ISO 14971:2012	EN 13641:2002	EN ISO 18113-2:2011
EN ISO 17511:2003			

**First Start of CE-MARK:** May 26, 2022

**Signature:** General Director

**Place, Date of Issue:** Shenzhen, May 26, 2022

## Declaration of Conformity

**Manufacturer:**

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

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Tel: +49-40-2513175 Fax: +49-40-255726

**Notified Body:**

CeCert Sp. z o.o.  
Address: ul. Żurawia 32/34 lok.49 Warszawa, Poland  
Identification Number: 2934

**EC Certificate No.:** CeCert/131/W/E.1, CeCert/132/W/E.1

**Validity Period:** 25.05.2022 – 26.05.2025

**Product Name:**

MAGLUMI<sup>®</sup> HBeAg (CLIA) Controls 160201136MT

**Classification:**

List A (IVDD 98/79/EC, Annex II)

**Conformity Assessment Route:** Annex IV (IVDD 98/79/EC)

We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive:**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

**Standards Applied:**

EN 13612:2002	EN ISO 13485:2016	EN ISO 15223-1:2016	EN ISO 18113-1:2011
EN ISO 23640:2015	EN ISO 14971:2012	EN 13641:2002	EN ISO 18113-2:2011
EN ISO 17511:2003			

**First Start of CE-MARK:** May 26, 2022

**Signature:** General Director



**Place, Date of Issue:** Shenzhen, May 26, 2022





## Declaration of Conformity

**Manufacturer:**

Shenzhen New Industries Biomedical Engineering Co., Ltd.  
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**Notified Body:**

CeCert Sp. z o.o.  
ul. Żurawia 32/34 lok.49 Warszawa, Poland  
Identification Number: 2934

**EC Certificate No.:** CeCert/131/W/E.1, CeCert/132/W/E.1

**Validity Period:** 25.05.2022 – 26.05.2025

**Product Name:**

MAGLUMI<sup>®</sup> HBeAg (CLIA) 130210011M (100 Tests/kit), 130610011M (50 Tests/kit),  
130710011M (30 Tests/kit)

**Classification:**

List A (IVDD 98/79/EC, Annex II)

**Conformity Assessment Route:** Annex IV (IVDD 98/79/EC)

We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive:**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

**Standards Applied:**

EN 13612:2002	EN ISO 13485:2016	EN ISO 15223-1:2016	EN ISO 18113-1:2011
EN ISO 23640:2015	EN ISO 14971:2012	EN 13641:2002	EN ISO 18113-2:2011
EN ISO 17511:2003			

**First Start of CE-MARK:** May 26, 2022

**Signature:** Managing Director

**Place, Date of Issue:** Shenzhen, May 26, 2022

## Declaration of Conformity

**Manufacturer:**

Shenzhen New Industries Biomedical Engineering Co., Ltd.  
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**European Representative:**

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**Notified Body:**

CeCert Sp. z o.o.  
Address: ul. Żurawia 32/34 lok.49 Warszawa, Poland  
Identification Number: 2934

**EC Certificate No.:** CeCert/133/W/E.1, CeCert/134/W/E.1

**Validity Period:** 25.05.2022 – 26.05.2025

**Product Name:**

MAGLUMI<sup>®</sup> Anti-HBc IgM (CLIA) Controls 160201155MT

**Classification:**

List A (IVDD 98/79/EC, Annex II)

**Conformity Assessment Route:** Annex IV (IVDD 98/79/EC)

We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive:**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

**Standards Applied:**

EN 13612:2002	EN ISO 13485:2016	EN ISO 15223-1:2016	EN ISO 18113-1:2011
EN ISO 23640:2015	EN ISO 14971:2012	EN 13641:2002	EN ISO 18113-2:2011
EN ISO 17511:2003			

**First Start of CE-MARK:** May 26, 2022

**Signature:** General Director



**Place, Date of Issue:** Shenzhen, May 26, 2022





## Declaration of Conformity

**Manufacturer:**

Shenzhen New Industries Biomedical Engineering Co., Ltd.  
No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China  
Tel: +86-755-21536601 Fax: +86-755-28292740

**European Representative:**

Shanghai International Holding Corp. GmbH (Europe)  
Address: Eiffestrasse 80, 20537 Hamburg, Germany  
Tel: +49-40-2513175 Fax: +49-40-255726

**Notified Body:**

CeCert Sp. z o.o.  
Address: ul. Żurawia 32/34 lok.49 Warszawa, Poland  
Identification Number: 2934

**EC Certificate No.:** CeCert/133/W/E.1, CeCert/134/W/E.1

**Validity Period:** 25.05.2022 – 26.05.2025

**Product Name:**

MAGLUMI<sup>®</sup> Anti-HBc IgM (CLIA) 130210014M (100 Tests/kit), 130610014M (50 Tests/kit),  
130710014M (30 Tests/kit)

**Classification:**

List A (IVDD 98/79/EC, Annex II)

**Conformity Assessment Route:** Annex IV (IVDD 98/79/EC)

We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive:**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

**Standards Applied:**

EN 13612:2002	EN ISO 13485:2016	EN ISO 15223-1:2016	EN ISO 18113-1:2011
EN ISO 23640:2015	EN ISO 14971:2012	EN 13641:2002	EN ISO 18113-2:2011
EN ISO 17511:2003			

**First Start of CE-MARK:** May 26, 2022

**Signature:** General Director

**Place, Date of Issue:** Shenzhen, May 26, 2022

## Declaration of Conformity

**Manufacturer:**

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

Shanghai International Holding Corp. GmbH (Europe)  
Address: Eiffestrasse 80, 20537 Hamburg, Germany  
Tel: +49-40-2513175 Fax: +49-40-255726

**Notified Body:**

TüV SüD Product Service GmbH  
Zertifizierstelle Ridlerstraße 65- 80339 München Germany  
Identification Number: 0123

**EC Certificate No.:** V7 105113 0003 Rev. 00; V1 105113 0002 Rev. 03

**Product Name:**

Anti-HCV (CLIA) 130210015M (100 tests/kit), 130610015M (50 tests/kit)

**Classification:**

List A (IVDD 98/79/EC, Annex II)

**Conformity Assessment Route:** Annex IV (IVDD 98/79/EC)

We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on *in vitro* diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive:**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

**Standards Applied:**

EN 13612:2002	EN ISO 13485:2016	EN ISO 15223-1:2016	EN ISO 18113-1:2011
EN ISO 23640:2015	EN ISO 14971:2012	EN 13641:2002	EN ISO 18113-2:2011
EN ISO 17511:2003	2009/886/EC		

**First Start of CE-MARK:** July 22, 2019

**Signature:** General Director



**Place, Date of Issue:** Shenzhen, Aug. 12, 2022



## Declaration of Conformity

**Manufacturer:**

Shenzhen New Industries Biomedical Engineering Co., Ltd.  
No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China  
Tel: +86-755-21536601 Fax: +86-755-28292740

**European Representative:**

Shanghai International Holding Corp. GmbH (Europe)  
Address: Eiffestrasse 80, 20537 Hamburg, Germany  
Tel: +49-40-2513175 Fax: +49-40-255726

**Notified Body:**

TüV SÜD Product Service GmbH  
Zertifizierstelle Ridlerstraße 65- 80339 München Germany  
Identification Number: 0123

EC Certificate No.: V7 105113 0004 Rev. 00; V1 105113 0002 Rev. 03

**Product Name:**

HIV Ab/Ag Combi (CLIA) 130219008M (100 tests/kit), 130619008M (50 tests/kit)

**Brand Name:** MAGLUMI®

**Classification:**

List A (IVDD 98/79/EC, Annex II)

**Conformity Assessment Route:** Annex IV (IVDD 98/79/EC)

We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive:**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

**Standards Applied:**

EN 13612:2002	EN ISO 13485:2016	EN ISO 15223-1:2016	EN ISO 18113-1:2011
EN ISO 23640:2015	EN ISO 14971:2012	EN 13641:2002	EN ISO 18113-2:2011
EN ISO 17511:2003			

**First Start of CE-MARK:** April 19, 2021

**Valid Period:** as the valid period of EC certificate above

**Signature:** General Director



**Place, Date of Issue:** Shenzhen, Aug. 12, 2022

## Declaration of Conformity

**Manufacturer:**

Shenzhen New Industries Biomedical Engineering Co., Ltd.  
No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China  
Tel: +86-755-21536601 Fax: +86-755-28292740

**European Representative:**

Shanghai International Holding Corp. GmbH (Europe)  
Address: Eiffestrasse 80, 20537 Hamburg, Germany  
Tel: +49-40-2513175 Fax: +49-40-255726

**Notified Body:**

CeCert Sp. z o.o.  
Address: ul. Żurawia 32/34 lok.49 Warszawa, Poland  
Identification Number: 2934

**EC Certificate No.:** CeCert/135/W/E.1, CeCert/136/W/E.1

**Validity Period:** 25.05.2022 – 26.05.2025

**Product Name:**

MAGLUMI<sup>®</sup> Anti-HBe (CLIA) Controls 160201452MT

**Classification:**

List A (IVDD 98/79/EC, Annex II)

**Conformity Assessment Route:** Annex IV (IVDD 98/79/EC)

We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on *in vitro* diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive:**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

**Standards Applied:**

EN 13612:2002	EN ISO 13485:2016	EN ISO 15223-1:2016	EN ISO 18113-1:2011
EN ISO 23640:2015	EN ISO 14971:2012	EN 13641:2002	EN ISO 18113-2:2011
EN ISO 17511:2003			

**First Start of CE-MARK:** May 26, 2022

**Signature:** General Director



**Place, Date of Issue:** Shenzhen, May 26, 2022



## Declaration of Conformity

**Manufacturer:**

Shenzhen New Industries Biomedical Engineering Co., Ltd.  
No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China  
Tel: +86-755-21536601 Fax: +86-755-28292740

**European Representative:**

Shanghai International Holding Corp. GmbH (Europe)  
Address: Eiffestrasse 80, 20537 Hamburg, Germany  
Tel: +49-40-2513175 Fax: +49-40-255726

**Notified Body:**

CeCert Sp. z o.o.  
Address: ul. Żurawia 32/34 lok.49 Warszawa, Poland  
Identification Number: 2934

**EC Certificate No.:** CeCert/135/W/E.1, CeCert/136/W/E.1

**Validity Period:** 25.05.2022 – 26.05.2025

**Product Name:**

MAGLUMI<sup>®</sup> Anti-HBe (CLIA) 130210022M (100 Tests/kit), 130610022M (50 Tests/kit),  
130710022M (30 Tests/kit)

**Classification:**

List A (IVDD 98/79/EC, Annex II)

**Conformity Assessment Route:** Annex IV (IVDD 98/79/EC)

We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on *in vitro* diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive:**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

**Standards Applied:**

EN 13612:2002	EN ISO 13485:2016	EN ISO 15223-1:2016	EN ISO 18113-1:2011
EN ISO 23640:2015	EN ISO 14971:2012	EN 13641:2002	EN ISO 18113-2:2011
EN ISO 17511:2003			

**First Start of CE-MARK:** May 26, 2022

**Signature:** General Director



**Place, Date of Issue:** Shenzhen, May 26, 2022



## Declaration of Conformity

**Manufacturer:**

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

Shanghai International Holding Corp. GmbH (Europe)  
Address: Eiffestrasse 80, 20537 Hamburg, Germany  
Tel: +49-40-2513175 Fax: +49-40-255726

**Notified Body:**

CeCert Sp. z o.o.  
Address: ul. Żurawia 32/34 lok.49 Warszawa, Poland  
Identification Number: 2934

**EC Certificate No.:** CeCert/137/W/E.1, CeCert/138/W/E.1

**Validity Period:** 25.05.2022 – 26.05.2025

**Product Name:**

MAGLUMI<sup>®</sup> Anti-HBc (CLIA) Controls 160201453MT

**Classification:**

List A (IVDD 98/79/EC, Annex II)

**Conformity Assessment Route:** Annex IV (IVDD 98/79/EC)

We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive:**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

**Standards Applied:**

EN 13612:2002	EN ISO 13485:2016	EN ISO 15223-1:2016	EN ISO 18113-1:2011
EN ISO 23640:2015	EN ISO 14971:2012	EN 13641:2002	EN ISO 18113-2:2011
EN ISO 17511:2003			

**First Start of CE-MARK:** May 26, 2022

**Signature:** General Director

**Place, Date of Issue:** Shenzhen, May 26, 2022



## Declaration of Conformity

**Manufacturer:**

Shenzhen New Industries Biomedical Engineering Co., Ltd.  
No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China  
Tel: +86-755-21536601 Fax: +86-755-28292740

**European Representative:**

Shanghai International Holding Corp. GmbH (Europe)  
Address: Eiffestrasse 80, 20537 Hamburg, Germany  
Tel: +49-40-2513175 Fax: +49-40-255726

**Notified Body:**

CeCert Sp. z o.o.  
Address: ul. Żurawia 32/34 lok.49 Warszawa, Poland  
Identification Number: 2934

**EC Certificate No.:** CeCert/137/W/E.1 ,CeCert/138/W/E.1

**Validity Period:** 25.05.2022 – 26.05.2025

**Product Name:**

MAGLUMI<sup>®</sup> Anti-HBc (CLIA) 130210023M (100 Tests/kit), 130610023M (50 Tests/kit),  
130710023M: (30 Tests/kit)

**Classification:**

List A (IVDD 98/79/EC, Annex II)

**Conformity Assessment Route:** Annex IV (IVDD 98/79/EC)

We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive:**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

**Standards Applied:**

EN 13612:2002	EN ISO 13485:2016	EN ISO 15223-1:2016	EN ISO 18113-1:2011
EN ISO 23640:2015	EN ISO 14971:2012	EN 13641:2002	EN ISO 18113-2:2011
EN ISO 17511:2003			

**First Start of CE-MARK:** May 26, 2022

**Signature:** General Director



**Place, Date of Issue:** Shenzhen, May 26, 2022





## Declaration of Conformity

**Manufacturer:**

Shenzhen New Industries Biomedical Engineering Co., Ltd.  
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**European Representative:**

Shanghai International Holding Corp. GmbH (Europe)  
Eiffestrasse 80, 20537 Hamburg, Germany  
Tel: +49-40-2513175 Fax: +49-40-255726

**Product Name:**

Chemiluminescent Immunoassay Diagnostic Kits (Product identifications see the attachment)

**Classification:**

Other device, not in annex II, not for self-testing, not for performance evaluation.

**Conformity Assessment Route:** Annex III (IVDD 98/79/EC)

We herewith declare under sole responsibility that the following mentioned products meet the provisions of the Council Directive 98/79/EC on *in vitro* diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive:**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

**Standards Applied:**

EN 13612:2002      EN ISO 13485:2016      EN ISO 15223-1:2016      EN ISO 18113-1:2011  
EN ISO 23640:2015      EN ISO 14971:2012      EN 13641:2002      EN ISO 18113-2:2011  
EN ISO 17511:2003

**First Start of CE-MARK:** Sep. 25, 2018

**Signature:** Managing Director

**Place, Date of Issue:** Shenzhen, Dec. 09, 2019



## Attachment

Item	Product Name	Model	Cat. No.
1	T3 (CLIA)	100 tests	130203003M
		50 tests	130603003M
2	T4 (CLIA)	100 tests	130203002M
		50 tests	130603002M
3	FT3 (CLIA)	100 tests	130203005M
		50 tests	130603005M
4	FT4 (CLIA)	100 tests	130203004M
		50 tests	130603004M
5	TSH (CLIA)	100 tests	130203001M
		50 tests	130603001M
6	Rev T3 (CLIA)	100 tests	130203010M
		50 tests	130603010M
7	TGA (CLIA)	100 tests	130203007M
		50 tests	130603007M
8	TMA (CLIA)	100 tests	130203008M
		50 tests	130603008M
9	TG (CLIA)	100 tests	130203006M
		50 tests	130603006M
10	TRAb (CLIA)	100 tests	130203009M
		50 tests	130603009M
11	FSH (CLIA)	100 tests	130202001M
		50 tests	130602001M
12	LH (CLIA)	100 tests	130202002M
		50 tests	130602002M
13	PRL (CLIA)	100 tests	130202006M
		50 tests	130602006M
14	PRG (CLIA)	100 tests	130202009M
		50 tests	130602009M
15	Estradiol (CLIA)	100 tests	130202007M
		50 tests	130602007M
16	Testosterone (CLIA)	100 tests	130202010M
		50 tests	130602010M
17	HCG/ $\beta$ -HCG (CLIA)	100 tests	130202003M
		50 tests	130602003M
18	free Estriol (CLIA)	100 tests	130202008M
		50 tests	130602008M
19	free Testosterone (CLIA)	100 tests	130202011M
		50 tests	130602011M
20	Insulin (CLIA)	100 tests	130205002M
		50 tests	130605002M
21	C-Peptide (CLIA)	100 tests	130205001M
		50 tests	130605001M
22	NSE (CLIA)	100 tests	130201016M
		50 tests	130601016M
23	CA 125 (CLIA)	100 tests	130201009M
		50 tests	130601009M
24	CEA (CLIA)	100 tests	130201003M
		50 tests	130601003M
25	AFP (CLIA)	100 tests	130201002M
		50 tests	130601002M
26	Ferritin (CLIA)	100 tests	130201001M
		50 tests	130601001M
27	IgG (serum analysis) (CLIA)	100 tests	130208005M
		50 tests	130608005M
28	IgG (urine analysis) (CLIA)	100 tests	130208006M





		50 tests	130608006M
29	Albumin (CLIA)	100 tests	130204002M
		50 tests	130604002M
30	$\beta_2$ -MG (CLIA)	100 tests	130204001M
		50 tests	130604001M
31	Digoxin (CLIA)	100 tests	130207002M
		50 tests	130607002M
32	GH (CLIA)	100 tests	130298001M
		50 tests	130698001M
33	Cortisol (CLIA)	100 tests	130298002M
		50 tests	130698002M
34	Myoglobin (CLIA)	100 tests	130206003M
		50 tests	130606003M
35	CA 50 (CLIA)	100 tests	130201012M
		50 tests	130601012M
36	CA 19-9 (CLIA)	100 tests	130201011M
		50 tests	130601011M
37	CA 15-3 (CLIA)	100 tests	130201010M
		50 tests	130601010M
38	Proinsulin (CLIA)	100 tests	130205004M
		50 tests	130605004M
39	IgE (CLIA)	100 tests	130208001M
		50 tests	130608001M
40	IgA (urine analysis) (CLIA)	100 tests	130208004M
		50 tests	130608004M
41	IgA (serum analysis) (CLIA)	100 tests	130208003M
		50 tests	130608003M
42	IgM (CLIA)	100 tests	130208002M
		50 tests	130608002M
43	IAA (CLIA)	100 tests	130205003M
		50 tests	130605003M
44	CRP (CLIA)	100 tests	130216002M
		50 tests	130616002M
45	ACTH (CLIA)	100 tests	130298003M
		50 tests	130698003M
46	CK-MB (CLIA)	100 tests	130206001M
		50 tests	130606001M
47	S-100 (CLIA)	100 tests	130201017M
		50 tests	130601017M
48	Laminin (CLIA)	100 tests	130209004M
		50 tests	130609004M
49	C IV (CLIA)	100 tests	130209003M
		50 tests	130609003M
50	HA (CLIA)	100 tests	130209001M
		50 tests	130609001M
51	PIIIP N-P (CLIA)	100 tests	130209002M
		50 tests	130609002M
52	CSA (CLIA)	100 tests	130207001M
		50 tests	130607001M
53	Aldosterone (CLIA)	100 tests	130206007M
		50 tests	130606007M
54	Troponin I (CLIA)	100 tests	130206002M
		50 tests	130606002M
55	CA 242 (CLIA)	100 tests	130201014M
		50 tests	130601014M
56	CYFRA 21-1 (CLIA)	100 tests	130201013M
		50 tests	130601013M





57	SCCA(CLIA)	100 tests	130201018M
		50 tests	130601018M
58	Intact PTH(CLIA)	100 tests	130211001M
		50 tests	130611001M
59	Calcitonin (CLIA)	100 tests	130211002M
		50 tests	130611002M
60	FA (CLIA)	100 tests	130213001M
		50 tests	130613001M
61	CA 72-4 (CLIA)	100 tests	130201015M
		50 tests	130601015M
62	PCT (CLIA)	100 tests	130216001M
		50 tests	130616001M
63	GAD65 (CLIA)	100 tests	130205005M
		50 tests	130605005M
64	Cholyglycine (CLIA)	100 tests	130209005M
		50 tests	130609005M
65	EBV EA IgG (CLIA)	100 tests	130215001M
		50 tests	130615001M
66	EBV NA IgG (CLIA)	100 tests	130215006M
		50 tests	130615006M
67	HSV-2 IgG (CLIA)	100 tests	130212008M
		50 tests	130612008M
68	HSV-1/2 IgG (CLIA)	100 tests	130212007M
		50 tests	130612007M
69	EBV VCA IgG (CLIA)	100 tests	130215003M
		50 tests	130615003M
70	NT-proBNP (CLIA)	100 tests	130206004M
		50 tests	130606004M
71	PAP (CLIA)	100 tests	130201006M
		50 tests	130601006M
72	HSV-1/2 IgM (CLIA)	100 tests	130212009M
		50 tests	130612009M
73	EBV VCA IgM (CLIA)	100 tests	130215004M
		50 tests	130615004M
74	EBV VCA IgA (CLIA)	100 tests	130215005M
		50 tests	130615005M
75	Osteocalcin (CLIA)	100 tests	130211003M
		50 tests	130611003M
76	EBV EA IgA (CLIA)	100 tests	130215002M
		50 tests	130615002M
77	TPA-snibe (CLIA)	100 tests	130201007M
		50 tests	130601007M
78	A I (CLIA)	100 tests	130206005M
		50 tests	130606005M
79	A II (CLIA)	100 tests	130206006M
		50 tests	130606006M
80	FK 506 (CLIA)	100 tests	130207003M
		50 tests	130607003M
81	PG I (CLIA)	100 tests	130201019M
		50 tests	130601019M
82	PG II (CLIA)	100 tests	130201020M
		50 tests	130601020M
83	DHEA-S (CLIA)	100 tests	130202012M
		50 tests	130602012M
84	Vitamin B12 (CLIA)	100 tests	130213002M
		50 tests	130613002M
85	IGF-I (CLIA)	100 tests	130205007M



		50 tests	130605007M
86	Anti-TPO (CLIA)	100 tests	130203011M
		50 tests	130603011M
87	D-Dimer (CLIA)	100 tests	130206008M
		50 tests	130606008M
88	25-OH Vitamin D (CLIA)	100 tests	130211004M
		50 tests	130611004M
89	ICA (CLIA)	100 tests	130205006M
		50 tests	130605006M
90	hs-cTnI (CLIA)	100 tests	130206014M
		50 tests	130606014M
91	Anti-IA2 (CLIA)	100 tests	130205008M
		50 tests	130605008M
92	Lp-PLA2 (CLIA)	100 tests	130206015M
		50 tests	130606015M
93	H.pylori IgG (CLIA)	100 tests	130201021M
		50 tests	130601021M
94	Gastrin-17 (CLIA)	100 tests	130201022M
		50 tests	130601022M
95	Syphilis (CLIA)	100 tests	130219003M
		50 tests	130619003M
96	Anti-HAV (CLIA)	100 tests	130210007M
		50 tests	130610007M
97	HAV IgM (CLIA)	100 tests	130210008M
		50 tests	130610008M
98	17-OH PROGESTERONE (CLIA)	100 tests	130298004M
		50 tests	130698004M
99	Chagas (CLIA)	100 tests	130219001M
		50 tests	130619001M
100	Direct Renin (CLIA)	100 tests	130206011M
		50 tests	130606011M
101	AMH (CLIA)	100 tests	130202014M
		50 tests	130602014M
102	Anti-Scl-70 IgG (CLIA)	100 tests	130217005M
		50 tests	130617005M
103	Anti-Centromeres IgG (CLIA)	100 tests	130217006M
		50 tests	130617006M
104	Anti-M2-3E IgG (CLIA)	100 tests	130217007M
		50 tests	130617007M
105	Anti-Histones IgG (CLIA)	100 tests	130217008M
		50 tests	130617008M
106	Anti-Rib-P IgG (CLIA)	100 tests	130217010M
		50 tests	130617010M
107	Anti-nRNP/Sm IgG (CLIA)	100 tests	130217011M
		50 tests	130617011M
108	Anti-Sm IgG (CLIA)	100 tests	130217012M
		50 tests	130617012M
109	Anti-SS-A IgG (CLIA)	100 tests	130217013M
		50 tests	130617013M
110	Anti-SS-B IgG (CLIA)	100 tests	130217014M
		50 tests	130617014M
111	Anti-Jo-1 IgG (CLIA)	100 tests	130217009M
		50 tests	130617009M
112	HER-2 (CLIA)	100 tests	130201026M





113	IL-6 (CLIA)	50 tests	130601026M
		100 tests	130216004M
		50 tests	130616004M
114	ProGRP (CLIA)	100 tests	130201023M
		50 tests	130601023M
115	H-FABP (CLIA)	100 tests	130206012M
		50 tests	130606012M
116	Anti-CCP (CLIA)	100 tests	130217001M
		50 tests	130617001M
117	SHBG (CLIA)	100 tests	130202015M
		50 tests	130602015M
118	Anti-dsDNA IgG (CLIA)	100 tests	130217002M
		50 tests	130617002M
119	Androstenedione (CLIA)	100 tests	130202016M
		50 tests	130602016M
120	ANA Screen (CLIA)	100 tests	130217003M
		50 tests	130617003M
121	ENA Screen (CLIA)	100 tests	130217004M
		50 tests	130617004M
122	HE4 (CLIA)	100 tests	130201025M
		50 tests	130601025M
123	IGFBP-3 (CLIA)	100 tests	130298005M
		50 tests	130698005M
124	H.pylori IgA (CLIA)	100 tests	130201028M
		50 tests	130601028M
125	H.pylori IgM (CLIA)	100 tests	130201027M
		50 tests	130601027M
126	EBV NA IgA (CLIA)	100 tests	130215007M
		50 tests	130615007M
127	BNP (CLIA)	100 tests	130206016M
		50 tests	130606016M



## Declaration of Conformity

**Manufacturer:**

Shenzhen New Industries Biomedical Engineering Co., Ltd.  
No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China  
Tel: +86-755-21536601 Fax: +86-755-28292740

**European Representative:**

Shanghai International Holding Corp. GmbH (Europe)  
Eiffestrasse 80, 20537 Hamburg, Germany  
Tel: +49-40-2513175 Fax: +49-40-255726

**Product Name:**

Product identifications see the attachment

**Classification:**

Other device, not in annex II, not for self-testing, not for performance evaluation.

**Conformity Assessment Route:** Annex III (IVDD 98/79/EC)

We herewith declare under sole responsibility that the following mentioned products meet the provisions of the Council Directive 98/79/EC on *in vitro* diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive:**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

**Standards Applied:**

EN 13612:2002      EN ISO 13485:2016      EN ISO 15223-1:2016      EN ISO 18113-1:2011  
EN ISO 23640:2015      EN ISO 14971:2012      EN 13641:2002      EN ISO 18113-2:2011  
EN ISO 17511:2003

**First Start of CE-MARK:** Mar. 22, 2019

**Signature:** General Director



**Place, Date of Issue:** Shenzhen, Sept. 18, 2021

## Attachment

Item	Product Name	Cat. No.
1.	T3 (CLIA) Control 1	160201001M1
2.	T3 (CLIA) Control 2	160201001M2
3.	T4 (CLIA) Control 1	160201002M1
4.	T4 (CLIA) Control 2	160201002M2
5.	FT3 (CLIA) Control 1	160201003M1
6.	FT3 (CLIA) Control 2	160201003M2
7.	FT4 (CLIA) Control 1	160201004M1
8.	FT4 (CLIA) Control 2	160201004M2
9.	TSH (CLIA) Control 1	160201005M1
10.	TSH (CLIA) Control 2	160201005M2
11.	Rev T3 (CLIA) Control 1	160201006M1
12.	Rev T3 (CLIA) Control 2	160201006M2
13.	TGA (CLIA) Control 1	160201007M1
14.	TGA (CLIA) Control 2	160201007M2
15.	TMA (CLIA) Control 1	160201008M1
16.	TMA (CLIA) Control 2	160201008M2
17.	TG (CLIA) Control 1	160201009M1
18.	TG (CLIA) Control 2	160201009M2
19.	TRAb (CLIA) Control 1	160201010M1
20.	TRAb (CLIA) Control 2	160201010M2
21.	FSH (CLIA) Control 1	160201011M1
22.	FSH (CLIA) Control 2	160201011M2
23.	LH (CLIA) Control 1	160201012M1
24.	LH (CLIA) Control 2	160201012M2
25.	PRL (CLIA) Control 1	160201013M1
26.	PRL (CLIA) Control 2	160201013M2
27.	PRG (CLIA) Control 1	160201014M1
28.	PRG (CLIA) Control 2	160201014M2
29.	Estradiol (CLIA) Control 1	160201015M1
30.	Estradiol (CLIA) Control 2	160201015M2
31.	Testosterone (CLIA) Control 1	160201016M1
32.	Testosterone (CLIA) Control 2	160201016M2
33.	HCG/ $\beta$ -HCG (CLIA) Control 1	160201017M1
34.	HCG/ $\beta$ -HCG (CLIA) Control 2	160201017M2
35.	free Estriol (CLIA) Control 1	160201019M1
36.	free Estriol (CLIA) Control 2	160201019M2
37.	free Estriol (CLIA) Control 3	160201019M3
38.	free Testosterone (CLIA) Control 1	160201020M1
39.	free Testosterone (CLIA) Control 2	160201020M2
40.	Insulin (CLIA) Control 1	160201021M1
41.	Insulin (CLIA) Control 2	160201021M2



42.	C-Peptide (CLIA) Control 1	160201022M1
43.	C-Peptide (CLIA) Control 2	160201022M2
44.	NSE (CLIA) Control 1	160201023M1
45.	NSE (CLIA) Control 2	160201023M2
46.	CA 125 (CLIA) Control 1	160201024M1
47.	CA 125 (CLIA) Control 2	160201024M2
48.	CEA (CLIA) Control 1	160201025M1
49.	CEA (CLIA) Control 2	160201025M2
50.	AFP (CLIA) Control 1	160201026M1
51.	AFP (CLIA) Control 2	160201026M2
52.	Ferritin (CLIA) Control 1	160201028M1
53.	Ferritin (CLIA) Control 2	160201028M2
54.	IgG (serum analysis) (CLIA) Control 1	160201029M3
55.	IgG (serum analysis) (CLIA) Control 2	160201029M4
56.	IgG (urine analysis) (CLIA) Control 1	160201029M1
57.	IgG (urine analysis) (CLIA) Control 2	160201029M2
58.	Albumin (CLIA) Control 1	160201030M1
59.	Albumin (CLIA) Control 2	160201030M2
60.	$\beta_2$ -MG (CLIA) Control 1	160201031M1
61.	$\beta_2$ -MG (CLIA) Control 2	160201031M2
62.	Digoxin (CLIA) Control 1	160201032M1
63.	Digoxin (CLIA) Control 2	160201032M2
64.	GH (CLIA) Control 1	160201033M1
65.	GH (CLIA) Control 2	160201033M2
66.	Cortisol (CLIA) Control 1	160201034M1
67.	Cortisol (CLIA) Control 2	160201034M2
68.	Myoglobin (CLIA) Control 1	160201035M1
69.	Myoglobin (CLIA) Control 2	160201035M2
70.	CA 50 (CLIA) Control 1	160201037M1
71.	CA 50 (CLIA) Control 2	160201037M2
72.	CA 19-9 (CLIA) Control 1	160201038M1
73.	CA 19-9 (CLIA) Control 2	160201038M2
74.	CA 15-3 (CLIA) Control 1	160201039M1
75.	CA 15-3 (CLIA) Control 2	160201039M2
76.	Proinsulin (CLIA) Control 1	160201040M1
77.	Proinsulin (CLIA) Control 2	160201040M2
78.	IgE (CLIA) Control 1	160201041M1
79.	IgE (CLIA) Control 2	160201041M2
80.	IgA (serum analysis) (CLIA) Control 1	160201042M3
81.	IgA (serum analysis) (CLIA) Control 2	160201042M4
82.	IgA (urine analysis) (CLIA) Control 1	160201042M1
83.	IgA (urine analysis) (CLIA) Control 2	160201042M2



84.	IgM (CLIA) Control 1	160201043M1
85.	IgM (CLIA) Control 2	160201043M2
86.	IAA (CLIA) Control 1	160201044M1
87.	IAA (CLIA) Control 2	160201044M2
88.	CRP (CLIA) Control 1	160201045M1
89.	CRP (CLIA) Control 2	160201045M2
90.	ACTH (CLIA) Control 1	160201046M1
91.	ACTH (CLIA) Control 2	160201046M2
92.	CK-MB (CLIA) Control 1	160201047M1
93.	CK-MB (CLIA) Control 2	160201047M2
94.	S-100 (CLIA) Control 1	160201048M1
95.	S-100 (CLIA) Control 2	160201048M2
96.	Laminin (CLIA) Control 1	160201049M1
97.	Laminin (CLIA) Control 2	160201049M2
98.	C IV (CLIA) Control 1	160201050M1
99.	C IV (CLIA) Control 2	160201050M2
100.	HA (CLIA) Control 1	160201051M1
101.	HA (CLIA) Control 2	160201051M2
102.	PIIIP N-P (CLIA) Control 1	160201052M1
103.	PIIIP N-P (CLIA) Control 2	160201052M2
104.	CSA (CLIA) Control 1	160201058M1
105.	CSA (CLIA) Control 2	160201058M2
106.	Aldosterone (CLIA) Control 1	160201059M1
107.	Aldosterone (CLIA) Control 2	160201059M2
108.	Troponin I (CLIA) Control 1	160201060M1
109.	Troponin I (CLIA) Control 2	160201060M2
110.	CA 242 (CLIA) Control 1	160201061M1
111.	CA 242 (CLIA) Control 2	160201061M2
112.	CYFRA 21-1 (CLIA) Control 1	160201062M1
113.	CYFRA 21-1 (CLIA) Control 2	160201062M2
114.	SCCA (CLIA) Control 1	160201063M1
115.	SCCA (CLIA) Control 2	160201063M2
116.	Intact PTH (CLIA) Control 1	160201064M1
117.	Intact PTH (CLIA) Control 2	160201064M2
118.	Calcitonin (CLIA) Control 1	160201065M1
119.	Calcitonin (CLIA) Control 2	160201065M2
120.	FA (CLIA) Control 1	160201066M1
121.	FA (CLIA) Control 2	160201066M2
122.	CA 72-4 (CLIA) Control 1	160201067M1
123.	CA 72-4 (CLIA) Control 2	160201067M2
124.	PCT (CLIA) Control 1	160201068M1
125.	PCT (CLIA) Control 2	160201068M2

126.	GAD65 (CLIA) Control 1	160201069M1
127.	GAD65 (CLIA) Control 2	160201069M2
128.	Cholylglycine (CLIA) Control 1	160201070M1
129.	Cholylglycine (CLIA) Control 2	160201070M2
130.	EBV EA IgG (CLIA) Positive Control	160201072M1
131.	EBV EA IgG (CLIA) Negative Control	160201072M2
132.	EBV NA IgG (CLIA) Positive Control	160201073M1
133.	EBV NA IgG (CLIA) Negative Control	160201073M2
134.	HSV-2 IgG (CLIA) Positive Control	160201074M1
135.	HSV-2 IgG (CLIA) Negative Control	160201074M2
136.	HSV-1/2 IgG (CLIA) Positive Control	160201075M1
137.	HSV-1/2 IgG (CLIA) Negative Control	160201075M2
138.	EBV VCA IgG (CLIA) Positive Control	160201078M1
139.	EBV VCA IgG (CLIA) Negative Control	160201078M2
140.	NT-proBNP (CLIA) Control 1	160201079M1
141.	NT-proBNP (CLIA) Control 2	160201079M2
142.	PAP (CLIA) Control 1	160201080M1
143.	PAP (CLIA) Control 2	160201080M2
144.	EBV VCA IgM (CLIA) Positive Control	160201085M1
145.	EBV VCA IgM (CLIA) Negative Control	160201085M2
146.	EBV VCA IgA (CLIA) Positive Control	160201086M1
147.	EBV VCA IgA (CLIA) Negative Control	160201086M2
148.	Osteocalcin (CLIA) Control 1	160201088M1
149.	Osteocalcin (CLIA) Control 2	160201088M2
150.	EBV EA IgA (CLIA) Positive Control	160201090M1
151.	EBV EA IgA (CLIA) Negative Control	160201090M2
152.	TPA-snibe (CLIA) Control 1	160201091M1
153.	TPA-snibe (CLIA) Control 2	160201091M2
154.	A I (CLIA) Control 1	160201092M1
155.	A I (CLIA) Control 2	160201092M2
156.	A II (CLIA) Control 1	160201093M1
157.	A II (CLIA) Control 2	160201093M2
158.	FK 506 (CLIA) Control 1	160201094M1
159.	FK 506 (CLIA) Control 2	160201094M2
160.	PG I (CLIA) Control 1	160201095M1
161.	PG I (CLIA) Control 2	160201095M2
162.	PG II (CLIA) Control 1	160201096M1
163.	PG II (CLIA) Control 2	160201096M2
164.	DHEA-S (CLIA) Control 1	160201097M1
165.	DHEA-S (CLIA) Control 2	160201097M2
166.	Vitamin B12 (CLIA) Control 1	160201099M1
167.	Vitamin B12 (CLIA) Control 2	160201099M2



168.	IGF-I(CLIA) Control 1	160201100M1
169.	IGF-I(CLIA) Control 2	160201100M2
170.	Anti-TPO (CLIA) Control 1	160201101M1
171.	Anti-TPO (CLIA) Control 2	160201101M2
172.	D-Dimer (CLIA) Control 1	160201102M1
173.	D-Dimer (CLIA) Control 2	160201102M2
174.	25-OH Vitamin D (CLIA) Control 1	160201103M1
175.	25-OH Vitamin D (CLIA) Control 2	160201103M2
176.	ICA (CLIA) Control 1	160201104M1
177.	ICA (CLIA) Control 2	160201104M2
178.	hs-cTnI (CLIA) Control 1	160201105M1
179.	hs-cTnI (CLIA) Control 2	160201105M2
180.	Anti-IA2 (CLIA) Control 1	160201106M1
181.	Anti-IA2 (CLIA) Control 2	160201106M2
182.	Lp-PLA2 (CLIA) Control 1	160201107M1
183.	Lp-PLA2 (CLIA) Control 2	160201107M2
184.	Direct Renin (CLIA) Control 1	160201108M1
185.	Direct Renin (CLIA) Control 2	160201108M2
186.	AMH (CLIA) Control 1	160201109M1
187.	AMH (CLIA) Control 2	160201109M2
188.	H.pylori IgG (CLIA) Negative Control	160201110M1
189.	H.pylori IgG (CLIA) Positive Control 1	160201110M2
190.	H.pylori IgG (CLIA) Positive Control 2	160201110M3
191.	Gastrin-17 (CLIA) Control 1	160201111M1
192.	Gastrin-17 (CLIA) Control 2	160201111M2
193.	Syphilis (CLIA) Negative Control	160201115M1
194.	Syphilis (CLIA) Positive Control	160201115M2
195.	Chagas (CLIA) Negative Control	160201116M1
196.	Chagas (CLIA) Positive Control	160201116M2
197.	Anti-HAV (CLIA) Control 1	160201118M1
198.	Anti-HAV (CLIA) Control 2	160201118M2
199.	Anti-HAV (CLIA) Control 3	160201118M3
200.	HAV IgM (CLIA) Control 1	160201119M1
201.	HAV IgM (CLIA) Control 2	160201119M2
202.	HAV IgM (CLIA) Control 3	160201119M3
203.	17-OH PROGESTERONE (CLIA) Control 1	160201120M1
204.	17-OH PROGESTERONE (CLIA) Control 2	160201120M2
205.	H-FABP (CLIA) Control 1	160201121M1
206.	H-FABP (CLIA) Control 2	160201121M2
207.	Androstenedione (CLIA) Control 1	160201130M1
208.	Androstenedione (CLIA) Control 2	160201130M2
209.	H.pylori IgA (CLIA) Negative Control	160201163M1

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210.	H.pylori IgA (CLIA) Positive Control	160201163M2
211.	H.pylori IgM (CLIA) Negative Control	160201164M1
212.	H.pylori IgM (CLIA) Positive Control	160201164M2
213.	HSV-1/2 IgM (CLIA) Positive Control	160201084M1
214.	HSV-1/2 IgM (CLIA) Negative Control	160201084M2
215.	Immunoassay Control	1307010001 1307010002 1307010003 1307010004 1307010005 1307010006 1307010007 1307010008



## Declaration of Conformity

**Manufacturer:**

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

Shanghai International Holding Corp. GmbH (Europe)  
Eiffestrasse 80, 20537 Hamburg, Germany  
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**Product Name:**

Chemiluminescent Immunoassay Diagnostic Reagents and Controls (Product identifications see the attachment)

**Classification:**

Other device, not in annex II, not for self-testing, not for performance evaluation.

**Conformity Assessment Route:** Annex III (IVDD 98/79/EC)

We herewith declare under sole responsibility that the following mentioned products meet the provisions of the Council Directive 98/79/EC on *in vitro* diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive:**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

**Standards Applied:**

EN 13612:2002      EN ISO 13485:2016      EN ISO 15223-1:2016      EN ISO 18113-1:2011  
EN ISO 23640:2015      EN ISO 14971:2012      EN 13641:2002      EN ISO 18113-2:2011  
EN ISO 17511:2003

**First Start of CE-MARK:** Apr. 14, 2022

**Signature:** General Director



**Place, Date of Issue:** Shenzhen, May 25, 2022

**Attachment 1 Reagents**

Item	Product Name	Model	Cat. No.
1	Total T3 (CLIA)	100 tests/kit	130253003M
		50 tests/kit	130653003M
		30 tests/kit	130753003M
2	Total T4 (CLIA)	100 tests/kit	130253002M
		50 tests/kit	130653002M
		30 tests/kit	130753002M
3	Free T3 (CLIA)	100 tests/kit	130253005M
		50 tests/kit	130653005M
		30 tests/kit	130753005M
4	Free T4 (CLIA)	100 tests/kit	130253004M
		50 tests/kit	130653004M
		30 tests/kit	130753004M
5	TSH (CLIA)	100 tests/kit	130203023M
		50 tests/kit	130603023M
		30 tests/kit	130703023M
6	Rev T3 (CLIA)	100 tests/kit	130253010M
		50 tests/kit	130653010M
		30 tests/kit	130753010M
7	Anti-Tg (CLIA)	100 tests/kit	130253007M
		50 tests/kit	130653007M
		30 tests/kit	130753007M
8	Anti-TM (CLIA)	100 tests/kit	130253008M
		50 tests/kit	130653008M
		30 tests/kit	130753008M
9	Thyroglobulin (CLIA)	100 tests/kit	130253006M
		50 tests/kit	130653006M
		30 tests/kit	130753006M
10	TRAb (CLIA)	100 tests/kit	130253009M
		50 tests/kit	130653009M
		30 tests/kit	130753009M
11	Anti-TPO (CLIA)	100 tests/kit	130253011M
		50 tests/kit	130653011M
		30 tests/kit	130753011M
12	FSH (CLIA)	100 tests/kit	130252001M
		50 tests/kit	130652001M
		30 tests/kit	130752001M
13	LH (CLIA)	100 tests/kit	130252002M
		50 tests/kit	130652002M
		30 tests/kit	130752002M
14	Estradiol (CLIA)	100 tests/kit	130252007M
		50 tests/kit	130652007M
		30 tests/kit	130752007M
15	Testosterone (CLIA)	100 tests/kit	130252010M
		50 tests/kit	130652010M
		30 tests/kit	130752010M
16	Prolactin (CLIA)	100 tests/kit	130252006M



		50 tests/kit	130652006M
		30 tests/kit	130752006M
17	Progesterone (CLIA)	100 tests/kit	130252009M
		50 tests/kit	130652009M
		30 tests/kit	130752009M
		100 tests/kit	130252003M
18	Total $\beta$ HCG (CLIA)	50 tests/kit	130652003M
		30 tests/kit	130752003M
19	Free-Testosterone (CLIA)	100 tests/kit	130252011M
		50 tests/kit	130652011M
		30 tests/kit	130752011M
20	cTnI (CLIA)	100 tests/kit	130256002M
		50 tests/kit	130656002M
		30 tests/kit	130756002M
21	17 $\alpha$ -OH Progesterone (CLIA)	100 tests/kit	130270004M
		50 tests/kit	130670004M
		30 tests/kit	130770004M
22	S100 (CLIA)	100 tests/kit	130251017M
		50 tests/kit	130651017M
		30 tests/kit	130751017M
23	Insulin (CLIA)	100 tests/kit	130255002M
		50 tests/kit	130655002M
		30 tests/kit	130755002M
24	C-Peptide (CLIA)	100 tests/kit	130255001M
		50 tests/kit	130655001M
		30 tests/kit	130755001M
25	NSE (CLIA)	100 tests/kit	130201030M
		50 tests/kit	130601030M
		30 tests/kit	130701030M
26	CA 125 (CLIA)	100 tests/kit	130201031M
		50 tests/kit	130601031M
		30 tests/kit	130701031M
27	CEA (CLIA)	100 tests/kit	130201032M
		50 tests/kit	130601032M
		30 tests/kit	130701032M
28	AFP (CLIA)	100 tests/kit	130201033M
		50 tests/kit	130601033M
		30 tests/kit	130701033M
29	Ferritin (CLIA)	100 tests/kit	130251001M
		50 tests/kit	130651001M
		30 tests/kit	130751001M
30	CA 50 (CLIA)	100 tests/kit	130201036M
		50 tests/kit	130601036M
		30 tests/kit	130701036M
31	CA 19-9 (CLIA)	100 tests/kit	130201037M
		50 tests/kit	130601037M
		30 tests/kit	130701037M
32	CA 15-3 (CLIA)	100 tests/kit	130201038M

		50 tests/kit	130601038M
		30 tests/kit	130701038M
33	CA 242 (CLIA)	100 tests/kit	130201039M
		50 tests/kit	130601039M
		30 tests/kit	130701039M
34	CYFRA 21-1 (CLIA)	100 tests/kit	130201040M
		50 tests/kit	130601040M
		30 tests/kit	130701040M
35	SCCA (CLIA)	100 tests/kit	130201041M
		50 tests/kit	130601041M
		30 tests/kit	130701041M
36	Calcitonin (CLIA)	100 tests/kit	130261002M
		50 tests/kit	130661002M
		30 tests/kit	130761002M
37	FA (CLIA)	100 tests/kit	130263001M
		50 tests/kit	130663001M
		30 tests/kit	130763001M
38	CA 72-4 (CLIA)	100 tests/kit	130201042M
		50 tests/kit	130601042M
		30 tests/kit	130701042M
39	DHEA-S (CLIA)	100 tests/kit	130252012M
		50 tests/kit	130652012M
		30 tests/kit	130752012M
40	25-OH Vitamin D (CLIA)	100 tests/kit	130261004M
		50 tests/kit	130661004M
		30 tests/kit	130761004M
41	ICA (CLIA)	100 tests/kit	130205506M
		50 tests/kit	130605506M
		30 tests/kit	130705506M
42	Anti-IA2 (CLIA)	100 tests/kit	130205011M
		50 tests/kit	130605011M
		30 tests/kit	130705011M
43	Lp-PLA2 (CLIA)	100 tests/kit	130206515M
		50 tests/kit	130606515M
		30 tests/kit	130706515M
44	Direct Renin (CLIA)	100 tests/kit	130206511M
		50 tests/kit	130606511M
		30 tests/kit	130706511M
45	AMH (CLIA)	100 tests/kit	130252014M
		50 tests/kit	130652014M
		30 tests/kit	130752014M
46	H.pylori IgG (CLIA)	100 tests/kit	130201521M
		50 tests/kit	130601521M
		30 tests/kit	130701521M
47	Gastrin-17 (CLIA)	100 tests/kit	130201522M
		50 tests/kit	130601522M
		30 tests/kit	130701522M
48	H-FABP (CLIA)	100 tests/kit	130206512M



		50 tests/kit	130606512M
		30 tests/kit	130706512M
49	ProGRP (CLIA)	100 tests/kit	130201523M
		50 tests/kit	130601523M
		30 tests/kit	130701523M
50	Anti-CCP (CLIA)	100 tests/kit	130217501M
		50 tests/kit	130617501M
		30 tests/kit	130717501M
51	SHBG (CLIA)	100 tests/kit	130202515M
		50 tests/kit	130602515M
		30 tests/kit	130702515M
52	Anti-dsDNA IgG (CLIA)	100 tests/kit	130217502M
		50 tests/kit	130617502M
		30 tests/kit	130717502M
53	Androstenedione (CLIA)	100 tests/kit	130202516M
		50 tests/kit	130602516M
		30 tests/kit	130702516M
54	ANA Screen (CLIA)	100 tests/kit	130217503M
		50 tests/kit	130617503M
		30 tests/kit	130717503M
55	ENA Screen (CLIA)	100 tests/kit	130217504M
		50 tests/kit	130617504M
		30 tests/kit	130717504M
56	HE4 (CLIA)	100 tests/kit	130201525M
		50 tests/kit	130601525M
		30 tests/kit	130701525M
57	Anti-Scl-70 IgG (CLIA)	100 tests/kit	130217505M
		50 tests/kit	130617505M
		30 tests/kit	130717505M
58	Anti-Centromeres IgG (CLIA)	100 tests/kit	130217506M
		50 tests/kit	130617506M
		30 tests/kit	130717506M
59	Anti-Histones IgG (CLIA)	100 tests/kit	130217508M
		50 tests/kit	130617508M
		30 tests/kit	130717508M
60	Anti-Rib-P IgG (CLIA)	100 tests/kit	130217510M
		50 tests/kit	130617510M
		30 tests/kit	130717510M
61	Anti-Sm IgG (CLIA)	100 tests/kit	130217512M
		50 tests/kit	130617512M
		30 tests/kit	130717512M
62	Anti-SS-B IgG (CLIA)	100 tests/kit	130217514M
		50 tests/kit	130617514M
		30 tests/kit	130717514M
63	Anti-Jo-1 IgG (CLIA)	100 tests/kit	130217509M
		50 tests/kit	130617509M
		30 tests/kit	130717509M
64	HER-2 (CLIA)	100 tests/kit	130201526M

		50 tests/kit	130601526M
		30 tests/kit	130701526M
65	IL-6 (CLIA)	100 tests/kit	130216504M
		50 tests/kit	130616504M
		30 tests/kit	130716504M
66	IGFBP-3 (CLIA)	100 tests/kit	130298505M
		50 tests/kit	130698505M
		30 tests/kit	130798505M
67	BNP (CLIA)	100 tests/kit	130206516M
		50 tests/kit	130606516M
		30 tests/kit	130706516M
68	Aldosterone (CLIA)	100 tests/kit	130256007M
		50 tests/kit	130656007M
		30 tests/kit	130756007M
69	Anti-Sm/RNP IgG (CLIA)	100 tests/kit	130217511M
		50 tests/kit	130617511M
		30 tests/kit	130717511M
70	Anti-SS-A/Ro IgG (CLIA)	100 tests/kit	130217513M
		50 tests/kit	130617513M
		30 tests/kit	130717513M
71	AMA-M2 IgG (CLIA)	100 tests/kit	130217507M
		50 tests/kit	130617507M
		30 tests/kit	130717507M
72	Anti-HAV (CLIA)	100 tests/kit	130210024M
		50 tests/kit	130610024M
		30 tests/kit	130710024M
73	HAV IgM (CLIA)	100 tests/kit	130210025M
		50 tests/kit	130610025M
		30 tests/kit	130710025M
74	EBV NA IgA (CLIA)	100 tests/kit	130215008M
		50 tests/kit	130615008M
		30 tests/kit	130715008M
75	PAP (CLIA)	100 tests/kit	130251006M
		50 tests/kit	130651006M
		30 tests/kit	130751006M
76	Vitamin B12 (CLIA)	100 tests/kit	130263002M
		50 tests/kit	130663002M
		30 tests/kit	130763002M
77	IGF-I (CLIA)	100 tests/kit	130255007M
		50 tests/kit	130655007M
		30 tests/kit	130755007M
78	D-Dimer (CLIA)	100 tests/kit	130256008M
		50 tests/kit	130656008M
		30 tests/kit	130756008M
79	Laminin (CLIA)	100 tests/kit	130259004M
		50 tests/kit	130659004M
		30 tests/kit	130759004M
80	Cholyglycine (CLIA)	100 tests/kit	130259005M



		50 tests/kit	130659005M
		30 tests/kit	130759005M
81	Cortisol (CLIA)	100 tests/kit	130270002M
		50 tests/kit	130670002M
		30 tests/kit	130770002M
		100 tests/kit	130255003M
82	IAA (CLIA)	50 tests/kit	130655003M
		30 tests/kit	130755003M
		100 tests/kit	130266001M
83	PCT (CLIA)	50 tests/kit	130666001M
		30 tests/kit	130766001M
		100 tests/kit	130255004M
84	Proinsulin (CLIA)	50 tests/kit	130655004M
		30 tests/kit	130755004M
		100 tests/kit	130270003M
85	ACTH (CLIA)	50 tests/kit	130670003M
		30 tests/kit	130770003M
		100 tests/kit	130261001M
86	Intact PTH (CLIA)	50 tests/kit	130661001M
		30 tests/kit	130761001M
		100 tests/kit	130261003M
87	Osteocalcin (CLIA)	50 tests/kit	130661003M
		30 tests/kit	130761003M
		100 tests/kit	130262007M
88	HSV-1/2 IgG (CLIA)	50 tests/kit	130662007M
		30 tests/kit	130762007M
		100 tests/kit	130262009M
89	HSV-1/2 IgM (CLIA)	50 tests/kit	130662009M
		30 tests/kit	130762009M
		100 tests/kit	130257002M
90	Digoxin (CLIA)	50 tests/kit	130657002M
		30 tests/kit	130757002M
		100 tests/kit	130254002M
91	Albumin (CLIA)	50 tests/kit	130654002M
		30 tests/kit	130754002M
		100 tests/kit	130256003M
92	Myoglobin (CLIA)	50 tests/kit	130656003M
		30 tests/kit	130756003M
		100 tests/kit	130256001M
93	CK-MB (CLIA)	50 tests/kit	130656001M
		30 tests/kit	130756001M
		100 tests/kit	130256004M
94	NT-proBNP (CLIA)	50 tests/kit	130656004M
		30 tests/kit	130756004M
		100 tests/kit	130258001M
95	IgE (CLIA)	50 tests/kit	130658001M
		30 tests/kit	130758001M
		100 tests/kit	130251028M
96	H.pylori IgA (CLIA)	100 tests/kit	130251028M

		50 tests/kit	130651028M
		30 tests/kit	130751028M
97	H.pylori IgM (CLIA)	100 tests/kit	130251027M
		50 tests/kit	130651027M
		30 tests/kit	130751027M
98	EBV EA IgG (CLIA)	100 tests/kit	130265001M
		50 tests/kit	130665001M
		30 tests/kit	130765001M
99	EBV NA IgG (CLIA)	100 tests/kit	130265006M
		50 tests/kit	130665006M
		30 tests/kit	130765006M
100	EBV VCA IgG (CLIA)	100 tests/kit	130265003M
		50 tests/kit	130665003M
		30 tests/kit	130765003M
101	EBV VCA IgM (CLIA)	100 tests/kit	130265004M
		50 tests/kit	130665004M
		30 tests/kit	130765004M
102	EBV VCA IgA (CLIA)	100 tests/kit	130265005M
		50 tests/kit	130665005M
		30 tests/kit	130765005M
103	EBV EA IgA (CLIA)	100 tests/kit	130265002M
		50 tests/kit	130665002M
		30 tests/kit	130765002M
104	Syphilis (CLIA)	100 tests/kit	130269003M
		50 tests/kit	130669003M
		30 tests/kit	130769003M
105	CRP (CLIA)	100 tests/kit	130266002M
		50 tests/kit	130666002M
		30 tests/kit	130766002M
106	PIIIP N-P (CLIA)	100 tests/kit	130259002M
		50 tests/kit	130659002M
		30 tests/kit	130759002M
107	HSV-2 IgG (CLIA)	100 tests/kit	130262008M
		50 tests/kit	130662008M
		30 tests/kit	130762008M
108	hs-cTnI (CLIA)	100 tests/kit	130256014M
		50 tests/kit	130656014M
		30 tests/kit	130756014M
109	Unconjugated Estriol (CLIA)	100 tests/kit	130252008M
		50 tests/kit	130652008M
		30 tests/kit	130752008M
110	Hyaluronic Acid (CLIA)	100 tests/kit	130259001M
		50 tests/kit	130659001M
		30 tests/kit	130759001M
111	Growth Hormone (CLIA)	100 tests/kit	130270001M
		50 tests/kit	130670001M
		30 tests/kit	130770001M
112	Anti-GAD (CLIA)	100 tests/kit	130255005M



		50 tests/kit	130655005M
		30 tests/kit	130755005M
113	Tacrolimus (CLIA)	100 tests/kit	130257003M
		50 tests/kit	130657003M
		30 tests/kit	130757003M
114	Cyclosporine (CLIA)	100 tests/kit	130257001M
		50 tests/kit	130657001M
		30 tests/kit	130757001M
115	$\beta$ 2-Microglobulin (CLIA)	100 tests/kit	130254001M
		50 tests/kit	130654001M
		30 tests/kit	130754001M
116	TPA (CLIA)	100 tests/kit	130201043M
		50 tests/kit	130601043M
		30 tests/kit	130701043M
117	Pepsinogen I (CLIA)	100 tests/kit	130251019M
		50 tests/kit	130651019M
		30 tests/kit	130751019M
118	Pepsinogen II (CLIA)	100 tests/kit	130251020M
		50 tests/kit	130651020M
		30 tests/kit	130751020M
119	Col IV (CLIA)	100 tests/kit	130259003M
		50 tests/kit	130659003M
		30 tests/kit	130759003M
120	Angiotensin I (CLIA)	100 tests/kit	130256005M
		50 tests/kit	130656005M
		30 tests/kit	130756005M
121	Angiotensin II (CLIA)	100 tests/kit	130256006M
		50 tests/kit	130656006M
		30 tests/kit	130756006M
122	IgG (CLIA)	100 tests/kit	130258005M
		50 tests/kit	130658005M
		30 tests/kit	130758005M
123	IgA (CLIA)	100 tests/kit	130258004M
		50 tests/kit	130658004M
		30 tests/kit	130758004M
124	IgM (CLIA)	100 tests/kit	130258002M
		50 tests/kit	130658002M
		30 tests/kit	130758002M
125	hs-CRP (CLIA)	100 tests/kit	130206023M
		50 tests/kit	130606023M
		30 tests/kit	130706023M
126	Anti-IA2 (CLIA)	100 tests/kit	130205508M
		50 tests/kit	130605508M
		30 tests/kit	130705508M
127	2019-nCoV IgM (CLIA)	100 tests/kit	130219016M
128	2019-nCoV IgG (CLIA)	100 tests/kit	130219015M
129	SARS-CoV-2 S-RBD IgG (CLIA)	100 tests/kit	130219017M

		50 tests/kit	130619017M
130	SARS-CoV-2 Neutralizing Antibody (CLIA)	100 tests/kit	130219027M
		50 tests/kit	130619027M
131	SARS-CoV-2 Ag (CLIA)	100 tests/kit	130219026M
		50 tests/kit	130619026M
132	SARS-CoV-2 S-RBD IgG II (CLIA)	100 tests/kit	130269017M
		50 tests/kit	130669017M
		30 tests/kit	130769017M
133	Anti-ZnT8 (CLIA)	100 tests/kit	130205009M
		50 tests/kit	130605009M
		30 tests/kit	130705009M
134	PIVKA-II (CLIA)	100 tests/kit	130201029M
		50 tests/kit	130601029M
		30 tests/kit	130701029M
135	total PINP (CLIA)	100 tests/kit	130211005M
		50 tests/kit	130611005M
		30 tests/kit	130711005M
136	$\beta$ -CTx (CLIA)	100 tests/kit	130211006M
		50 tests/kit	130611006M
		30 tests/kit	130711006M
137	PIGF (CLIA)	100 tests/kit	130212010M
		50 tests/kit	130612010M
		30 tests/kit	130712010M
138	sFlt-1 (CLIA)	100 tests/kit	130212011M
		50 tests/kit	130612011M
		30 tests/kit	130712011M
139	HSV-1 IgG (CLIA)	100 tests/kit	130212012M
		50 tests/kit	130612012M
		30 tests/kit	130712012M
140	HSV-1 IgM (CLIA)	100 tests/kit	130212013M
		50 tests/kit	130612013M
		30 tests/kit	130712013M
141	HSV-2 IgM (CLIA)	100 tests/kit	130212014M
		50 tests/kit	130612014M
		30 tests/kit	130712014M
142	Serum Amyloid A (CLIA)	100 tests/kit	130216005M
		50 tests/kit	130616005M
		30 tests/kit	130716005M
143	TNF- $\alpha$ (CLIA)	100 tests/kit	130216006M
		50 tests/kit	130616006M



		30 tests/kit	130716006M
144	EPO (CLIA)	100 tests/kit	130213003M
		50 tests/kit	130613003M
		30 tests/kit	130713003M
145	T-Uptake (CLIA)	100 tests/kit	130203014M
		50 tests/kit	130603014M
		30 tests/kit	130703014M
146	MPO (CLIA)	100 tests/kit	130206021M
		50 tests/kit	130606021M
		30 tests/kit	130706021M
147	Anti-MPO IgG (CLIA)	100 tests/kit	130217015M
		50 tests/kit	130617015M
		30 tests/kit	130717015M
148	<i>Mycoplasma pneumoniae</i> IgG (CLIA)	100 tests/kit	130219009M
		50 tests/kit	130619009M
		30 tests/kit	130719009M
149	<i>Mycoplasma pneumoniae</i> IgM (CLIA)	100 tests/kit	130219011M
		50 tests/kit	130619011M
		30 tests/kit	130719011M
150	HEV IgG (CLIA)	100 tests/kit	130210028M
		50 tests/kit	130610028M
		30 tests/kit	130710028M
151	HEV IgM (CLIA)	100 tests/kit	130210029M
		50 tests/kit	130610029M
		30 tests/kit	130710029M
152	Thrombin-Antithrombin III Complex (CLIA)	100 tests/kit	130218001M
		50 tests/kit	130618001M
		30 tests/kit	130718001M
153	Thrombomodulin (CLIA)	100 tests/kit	130218002M
		50 tests/kit	130618002M
		30 tests/kit	130718002M
154	$\alpha$ 2-Plasmininhibitor-Plasmin Complex (CLIA)	100 tests/kit	130218003M
		50 tests/kit	130618003M
		30 tests/kit	130718003M
155	Tissue plasminogen activator-Plasminogen activator inhibitor Complex (CLIA)	100 tests/kit	130218004M
		50 tests/kit	130618004M
		30 tests/kit	130718004M
156	Homocysteine (CLIA)	100 test/kit	130206024M
		50 test/kit	130606024M
		30 test/kit	130706024M

157	Dengue virus NS1 Antigen (CLIA)	100 tests/kit	130219029M
		50 tests/kit	130619029M
		30 tests/kit	130719029M
158	Anti-Dengue Virus IgG (CLIA)	100 tests/kit	130219030M
		50 tests/kit	130619030M
		30 tests/kit	130719030M
159	Anti-Dengue Virus IgM (CLIA)	100 tests/kit	130219031M
		50 tests/kit	130619031M
		30 tests/kit	130719031M
160	Anti-Cardiolipin IgG (CLIA)	100 tests/kit	130217017M
		50 tests/kit	130617017M
		30 tests/kit	130717017M
161	Anti-Cardiolipin IgM (CLIA)	100 tests/kit	130217016M
		50 tests/kit	130617016M
		30 tests/kit	130717016M
162	Anti-β2-Glycoprotein 1 IgG (CLIA)	100 tests/kit	130217018M
		50 tests/kit	130617018M
		30 tests/kit	130717018M
163	Anti-β2-Glycoprotein 1 IgM (CLIA)	100 tests/kit	130217019M
		50 tests/kit	130617019M
		30 tests/kit	130717019M
164	Anti-tissue Transglutaminase IgA (CLIA)	100 tests/kit	130217020M
		50 tests/kit	130617020M
		30 tests/kit	130717020M
165	Anti-tissue Transglutaminase IgG (CLIA)	100 tests/kit	130217021M
		50 tests/kit	130617021M
		30 tests/kit	130717021M
166	Anti-DGP IgA (CLIA)	100 tests/kit	130217022M
		50 tests/kit	130617022M
		30 tests/kit	130717022M
167	Anti-DGP IgG (CLIA)	100 tests/kit	130217023M
		50 tests/kit	130617023M
		30 tests/kit	130717023M
168	GP73 (CLIA)	100 tests/kit	130209006M
		50 tests/kit	130609006M
		30 tests/kit	130709006M



**Attachment 2 Controls**

Item	Product Name	Model	Cat. No.
1	Total T3 (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201242MT
2	Total T4 (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201243MT
3	Free T3 (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201244MT
4	Free T4 (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201245MT
5	Rev T3 (CLIA) Controls	Control 1: 1×1.5 mL Control 2: 1×1.5 mL	160201246MT
6	Anti-Tg (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201247MT
7	TSH (CLIA) Controls	Control 1: 1×1.5 mL Control 2: 1×1.5 mL	160201241MT
8	Anti-TM (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201248MT
9	Thyroglobulin (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201249MT
10	TRAb (CLIA) Controls	Control 1: 1×2.0 mL Control 2: 1×2.0 mL	160201290MT
11	Anti-TPO (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201250MT
12	FSH (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201251MT
13	LH (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201252MT
14	Prolactin (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201253MT
15	Progesterone (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201254MT
16	Testosterone (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201255MT
17	Estradiol (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201256MT
18	Total β HCG (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201257MT
19	Free-Testosterone (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201258MT
20	DHEA-S (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201259MT
21	AMH (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201230MT

22	17 $\alpha$ -OH Progesterone (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201293MT
23	Insulin (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201264MT
24	C-Peptide (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201265MT
25	NSE (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201217MT
26	CA 125 (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201218MT
27	CEA (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201219MT
28	AFP (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201220MT
29	CA 50 (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201223MT
30	CA 19-9 (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201224MT
31	CA 15-3 (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201225MT
32	CA 242 (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201226MT
33	CYFRA 21-1 (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201227MT
34	SCCA (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201228MT
35	CA 72-4 (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201229MT
36	S100 (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201296MT
37	25-OH Vitamin D (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201262MT
38	Ferritin (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201263MT
39	FA (CLIA) Controls	Control 1: 1 $\times$ 2.0 mL Control 2: 1 $\times$ 2.0 mL	160201216MT
40	Calcitonin (CLIA) Controls	Control 1: 1 $\times$ 2.0 mL Control 2: 1 $\times$ 2.0 mL	160201291MT
41	cTnI (CLIA) Controls	Control 1: 1 $\times$ 2.0 mL Control 2: 1 $\times$ 2.0 mL	160201292MT
42	Aldosterone (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201295MT
43	Anti-CCP (CLIA) Controls	Control 1: 1 $\times$ 1.0 mL Control 2: 1 $\times$ 1.0 mL	160201404MT

44	ANA Screen (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201405MT
45	ENA Screen (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201406MT
46	Anti-dsDNA IgG (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201407MT
47	Anti-Histones IgG (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201408MT
48	Anti-Rib-P IgG (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201409MT
49	Anti-Sm/RNP IgG (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201410MT
50	Anti-Sm IgG (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201411MT
51	Anti-SS-A/Ro IgG (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201412MT
52	Anti-SS-B IgG (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201413MT
53	Anti-Jo-1 IgG (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201414MT
54	Anti-Scl-70 IgG (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201415MT
55	Anti-Centromeres IgG (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201416MT
56	AMA-M2 IgG (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201417MT
57	H-FABP (CLIA) Controls	Control 1: 1×2.0 mL Control 2: 1×2.0 mL	160201418MT
58	Lp-PLA2 (CLIA) Controls	Control 1: 1×2.0 mL Control 2: 1×2.0 mL	160201419MT
59	ProGRP (CLIA) Controls	Control 1: 1×2.0 mL Control 2: 1×2.0 mL	160201420MT
60	HE4 (CLIA) Controls	Control 1: 1×2.0 mL Control 2: 1×2.0 mL	160201421MT
61	HER-2 (CLIA) Controls	Control 1: 1×2.0 mL Control 2: 1×2.0 mL	160201422MT
62	Androstenedione (CLIA) Controls	Control 1: 1×2.0 mL Control 2: 1×2.0 mL	160201423MT
63	IL-6 (CLIA) Controls	Control 1: 1×2.0 mL Control 2: 1×2.0 mL	160201424MT
64	BNP (CLIA) Controls	Control 1: 1×2.0 mL Control 2: 1×2.0 mL	160201425MT
65	Gastrin-17 (CLIA) Controls	Control 1: 1×2.0 mL Control 2: 1×2.0 mL	160201426MT



66	SHBG (CLIA) Controls	Lyophilized Control 1: 1×1.0 mL Lyophilized Control 2: 1×1.0 mL	160201427MT
67	Direct Renin (CLIA) Controls	Control 1: 1×2.0 mL Control 2: 1×2.0 mL	160201428MT
68	IGFBP-3 (CLIA) Controls	Control 1: 1×2.0 mL Control 2: 1×2.0 mL	160201429MT
69	H.pylori IgG (CLIA) Controls	Negative Control: 1×2.0 mL Positive Control 1: 1×2.0 mL Positive Control 2: 1×2.0 mL	160201430MT
70	Anti-IA2 (CLIA) Controls	Control 1: 1×1.5 mL Control 2: 1×1.5 mL	1602011024MT
71	ICA (CLIA) Controls	Control 1: 1×2.0 mL Control 2: 1×2.0 mL	160201432MT
72	PCT (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201471MT
73	Vitamin B12 (CLIA) Controls	Control 1: 1×1.5 mL Control 2: 1×1.5 mL	160201459MT
74	IGF-I (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201460MT
75	Tacrolimus (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201485MT
76	Cyclosporine (CLIA) Controls	Control 1: 1×1.5 mL Control 2: 1×1.5 mL	160201486MT
77	Myoglobin (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201490MT
78	NT-proBNP (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201492MT
79	CK-MB (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201491MT
80	β2-Microglobulin (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201489MT
81	ACTH (CLIA) Controls	Control 1: 1×2.5 mL Control 2: 1×2.5 mL	160201473MT
82	Osteocalcin (CLIA) Controls	Control 1: 1×1.5 mL Control 2: 1×1.5 mL	160201475MT
83	Intact PTH (CLIA) Controls	Control 1: 1×1.5 mL Control 2: 1×1.5 mL	160201474MT
84	IAA (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201469MT
85	Cortisol (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201468MT
86	Laminin (CLIA) Controls	Control 1: 1×1.5 mL Control 2: 1×1.5 mL	160201462MT
87	Col IV (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201463MT

88	Hyaluronic Acid (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201464MT
89	PHIP N-P (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201465MT
90	Cholyglycine (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201466MT
91	Growth Hormone (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201467MT
92	Anti-GAD (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201470MT
93	Digoxin (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201487MT
94	Unconjugated Estriol (CLIA) Controls	Control 1: 1×1.5 mL Control 2: 1×1.5 mL Control 3: 1×1.5 mL	160201260MT
95	Albumin (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201488MT
96	PAP (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201456MT
97	Pepsinogen I (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201457MT
98	Pepsinogen II (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201458MT
99	Angiotensin I (CLIA) Controls	Control 1: 1×1.5 mL Control 2: 1×1.5 mL	160201495MT
100	Angiotensin II (CLIA) Controls	Control 1: 1×1.5 mL Control 2: 1×1.5 mL	160201496MT
101	hs-cTnI (CLIA) Controls	Control 1: 1×1.5 mL Control 2: 1×1.5 mL Control 3: 1×1.5 mL	160201493MT
102	D-Dimer (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201461MT
103	Proinsulin (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201472MT
104	hs-CRP (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL Control 3: 1×1.0 mL	160201494MT
105	CRP (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL Control 3: 1×1.0 mL	1602011019MT
106	IgE (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201498MT
107	IgA (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201499MT
108	IgG (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201497MT

109	IgM (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL	160201500MT
110	EBV VCA IgG (CLIA) Controls	Negative Control: 1×1.0 mL Positive Control: 1×1.0 mL	1602011003MT
111	EBV EA IgG (CLIA) Controls	Negative Control: 1×1.0 mL Positive Control: 1×1.0 mL	1602011001MT
112	EBV NA IgG (CLIA) Controls	Negative Control: 1×1.0 mL Positive Control: 1×1.0 mL	1602011002MT
113	HSV-2 IgG (CLIA) Controls	Negative Control: 1×1.0 mL Positive Control: 1×1.0 mL	160201479MT
114	EBV VCA IgM (CLIA) Controls	Negative Control: 1×1.0 mL Positive Control: 1×1.0 mL	1602011004MT
115	EBV VCA IgA (CLIA) Controls	Negative Control: 1×1.0 mL Positive Control: 1×1.0 mL	1602011005MT
116	EBV EA IgA (CLIA) Controls	Negative Control: 1×1.0 mL Positive Control: 1×1.0 mL	1602011006MT
117	HSV-1/2 IgG (CLIA) Controls	Negative Control: 1×1.0 mL Positive Control: 1×1.0 mL	160201480MT
118	HSV-1/2 IgM (CLIA) Controls	Negative Control: 1×1.0 mL Positive Control: 1×1.0 mL	160201484MT
119	Syphilis (CLIA) Controls	Negative Control: 1×2.0 mL Positive Control: 1×2.0 mL	1602011013MT
120	TPA (CLIA) Controls	Control 1: 1×1.5 mL Control 2: 1×1.5 mL	1602011012MT
121	EBV NA IgA (CLIA) Controls	Negative Control: 1×1.0 mL Positive Control: 1×1.0 mL	160201451MT
122	H.pylori IgA (CLIA) Controls	Negative Control: 1×1.0 mL Positive Control: 1×1.0 mL	1602011014MT
123	H.pylori IgM (CLIA) Controls	Negative Control: 1×1.0 mL Positive Control: 1×1.0 mL	1602011015MT
124	Anti-HAV (CLIA) Controls	Control 1: 1×1.0 mL Control 2: 1×1.0 mL Control 3: 1×1.0 mL	160201449MT
125	HAV IgM (CLIA) Controls	Negative Control: 1×1.0 mL Positive Control: 1×1.0 mL	160201450MT
126	Immunoassay Controls	Level 1: 1×5 mL Level 2: 1×5 mL Level 3: 1×5 mL	1601010051
		Level 1: 3×5 mL	1601010053
		Level 2: 3×5 mL	1601010055
		Level 3: 3×5 mL	1601010057



		Level 1: 2×5 mL Level 2: 2×5 mL Level 3: 2×5 mL	1601010052
		Level 1: 6×5 mL	1601010054
		Level 2: 6×5 mL	1601010056
		Level 3: 6×5 mL	1601010058
127	Anti-IA2 (CLIA) Controls	Control 1: 1×2.0 mL Control 2: 1×2.0 mL	160201431MT
128	Anti-ZnT8 (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201128MT
129	PIVKA-II (CLIA) Controls	Control 1: 1×2.0 mL, Control 2: 1×2.0 mL	160201150MT
130	total P1NP (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201153MT
131	β-CTx (CLIA) Controls	Control 1: 1×1.5 mL, Control 2: 1×1.5 mL	160201154MT
132	PIGF (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201157MT
133	sFlt-1 (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201158MT
134	HSV-1 IgG (CLIA) Controls	Negative Control: 1×2.0 mL, Positive Control: 1×2.0 mL	160201159MT
135	HSV-1 IgM (CLIA) Controls	Negative Control: 1×1.0 mL, Positive Control: 1×1.0 mL	160201160MT
136	HSV-2 IgM (CLIA) Controls	Negative Control: 1×1.0 mL, Positive Control: 1×1.0 mL	160201161MT
137	Serum Amyloid A (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201177MT
138	TNF-α (CLIA) Controls	Control 1: 1×1.5 mL, Control 2: 1×1.5 mL	160201178MT
139	EPO (CLIA) Controls	Control 1: 1×2.0 mL, Control 2: 1×2.0 mL	160201179MT
140	T-Uptake (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201180MT
141	MPO (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201187MT
142	Anti-MPO IgG (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201188MT
143	<i>Mycoplasma pneumoniae</i> IgG (CLIA) Controls	Negative Control: 1×1.0 mL, Positive Control: 1×1.0 mL	160201189MT
144	<i>Mycoplasma pneumoniae</i> IgM (CLIA) Controls	Negative Control: 1×1.0 mL, Positive Control: 1×1.0 mL	160201190MT
145	HEV IgG (CLIA) Controls	Negative Control: 1×1.0 mL, Positive Control: 1×1.0 mL	160201214MT
146	HEV IgM (CLIA) Controls	Negative Control: 1×1.0 mL, Positive Control: 1×1.0 mL	160201215MT
147	Thrombin-Antithrombin III Complex (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201234MT
148	Thrombomodulin (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201235MT
149	α2-Plasmininhibitor-Plasmin Complex (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201236MT

150	Tissue plasminogen activator-Plasminogen activator inhibitor Complex (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201237MT
151	Homocysteine (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201269MT
152	Dengue virus NS1 Antigen (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201401MT
153	Anti-Dengue Virus IgG (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201402MT
154	Anti-Dengue Virus IgM (CLIA) Controls	Negative Control: 1×1.0 mL, Positive Control: 1×1.0 mL	160201403MT
155	Anti-Cardiolipin IgG (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201436MT
156	Anti-Cardiolipin IgM (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201437MT
157	Anti-β2-Glycoprotein 1 IgG(CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201440MT
158	Anti-β2-Glycoprotein 1 IgM(CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201441MT
159	Anti-tissue Transglutaminase IgA (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201443MT
160	Anti-tissue Transglutaminase IgG (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201444MT
161	Anti-DGP IgA (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201445MT
162	Anti-DGP IgG (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	160201446MT
163	GP73 (CLIA) Controls	Control 1: 1×1.0 mL, Control 2: 1×1.0 mL	1602011009MT



## Declaration of Conformity

**Manufacturer:**

Shenzhen New Industries Biomedical Engineering Co., Ltd.  
No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China  
Tel: +86-755-21536601 Fax: +86-755-28292740

**European Representative:**

Lotus NL B.V.  
Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.  
Email: peter@lotusnl.com

**Product Name:**

Chemiluminescent Immunoassay Diagnostic Reagents (Product identifications see the attachment)

**Classification:**

Other device, not in annex II, not for self-testing, not for performance evaluation.

**Conformity Assessment Route:** Annex III (IVDD 98/79/EC)

We herewith declare under sole responsibility that the following mentioned products meet the provisions of the Council Directive 98/79/EC on *in vitro* diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive:**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

**Standards Applied:**

EN 13612:2002      EN ISO 13485:2016      EN ISO 15223-1:2016      EN ISO 18113-1:2011  
EN ISO 23640:2015      EN ISO 14971:2012      EN 13641:2002      EN ISO 18113-2:2011  
EN ISO 17511:2003

**First Start of CE-MARK:** May 25, 2022

**Signature:** General Director

**Place, Date of Issue:** Shenzhen, May 25, 2022





Attachment

Item	Product Name	Model	Cat. No.
1	Monkeypox Virus Ag (CLIA)	100 tests/kit	130219032M
		50 tests/kit	130619032M
		30 tests/kit	130719032M
2	Anti-Monkeypox Virus IgG (CLIA)	100 tests/kit	130219033M
		50 tests/kit	130619033M
		30 tests/kit	130719033M
3	Anti-Monkeypox Virus IgM (CLIA)	100 tests/kit	130219034M
		50 tests/kit	130619034M
		30 tests/kit	130719034M

## Declaration of Conformity

**Manufacturer:**

Shenzhen New Industries Biomedical Engineering Co., Ltd.  
No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China  
Tel: +86-755-21536601 Fax: +86-755-28292740

**European Representative:**

Shanghai International Holding Corp. GmbH (Europe)  
Eiffestrasse 80, 20537 Hamburg, Germany  
Tel: +49-40-2513175 Fax: +49-40-255726

**Notified Body:**

TüV SüD Product Service GmbH  
Zertifizierstelle Ridlerstraße 65- 80339 München Germany  
Identification Number: 0123

EC Certificate No.: V1 105113 0002 Rev. 03

**Product Name:**

Chemiluminescent Immunoassay Diagnostic Kits and Quality Controls (Product identifications see the attachment)

**Classification (IVDD, Annex II):**

List B (IVDD 98/79/EC)

**Conformity Assessment Route:** Annex IV (IVDD 98/79/EC)

We herewith declare under sole responsibility that the following mentioned products meet the provisions of the Council Directive 98/79/EC on *in vitro* diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive:**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

**Standards Applied:**

EN 13612:2002      EN ISO 13485:2016      EN ISO 15223-1:2016      EN ISO 18113-1:2011  
EN ISO 23640:2015      EN ISO 14971:2012      EN 13641:2002      EN ISO 18113-2:2011  
EN ISO 17511:2003

**First Start of CE-MARK:** April 15, 2021

**Signature:** General Director



**Place, Date of Issue:** Shenzhen, March 31, 2022

## Attachment

Item	Product Name	Model	Cat. No.
1	Total PSA (CLIA)	100 tests	130201004M
		50 tests	130601004M
2	f-PSA (CLIA)	100 tests	130201005M
		50 tests	130601005M
3	Toxo IgG (CLIA)	100 tests	130212001M
		50 tests	130612001M
4	Toxo IgM (CLIA)	100 tests	130212002M
		50 tests	130612002M
5	Rubella IgG (CLIA)	100 tests	130212003M
		50 tests	130612003M
6	Rubella IgM (CLIA)	100 tests	130212004M
		50 tests	130612004M
7	CMV IgG (CLIA)	100 tests	130212005M
		50 tests	130612005M
8	CMV IgM (CLIA)	100 tests	130212006M
		50 tests	130612006M
9	Total PSA (CLIA) Control 1	2 mL	160201027M1
10	Total PSA (CLIA) Control 2	2 mL	160201027M2
11	f-PSA (CLIA) Control 1	2 mL	160201036M1
12	f-PSA (CLIA) Control 2	2 mL	160201036M2
13	CMV IgG (CLIA) Positive Control	2 mL	160201071M1
14	CMV IgG (CLIA) Negative Control	2 mL	160201071M2
15	Rubella IgG (CLIA) Positive Control	2 mL	160201076M1
16	Rubella IgG (CLIA) Negative Control	2 mL	160201076M2
17	Toxo IgG (CLIA) Positive Control	2 mL	160201077M1
18	Toxo IgG (CLIA) Negative Control	2 mL	160201077M2
19	CMV IgM (CLIA) Positive Control	2 mL	160201081M1
20	CMV IgM (CLIA) Negative Control	2 mL	160201081M2
21	Toxo IgM (CLIA) Positive Control	2 mL	160201082M1
22	Toxo IgM (CLIA) Negative Control	2 mL	160201082M2
23	Rubella IgM (CLIA) Positive Control	2 mL	160201083M1
24	Rubella IgM (CLIA) Negative Control	2 mL	160201083M2
25	Tumor Marker Control	Level 1: 1×2 mL, Level 2: 1×2 mL, Level 3: 1×2 mL	1307011001
		Level 1: 3×2 mL	1307011002
		Level 2: 3×2 mL	1307011003
		Level 3: 3×2 mL	1307011004
		Level 1: 2×2 mL, Level 2: 2×2 mL, Level 3: 2×2 mL	1307011005
		Level 1: 6×2 mL	1307011006
		Level 2: 6×2 mL	1307011007
		Level 3: 6×2 mL	1307011008