



## EU Declaration of Conformity

In accordance with REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on *in vitro* diagnostic medical devices.

### 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  
SRN: CN-MF-000005655

### European Representative:

Shanghai International Holding Corp. GmbH (Europe)  
Eiffestrasse 80, 20537 Hamburg, Germany  
Tel: +49-40-2513175 Fax: +49-40-255726  
SRN: DE-AR-000000001

### Product Information:

Product name: Light Check  
Catalogue Number: 130299006M  
Basic UDI-DI: 69471455314VZ

### Intended purpose:

The Light Check is used for completing system test to monitor the status of MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (a)

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.

We, Shenzhen New Industries Biomedical Engineering Co., Ltd, declare under the sole responsibility that the above listed device(s) is/are in conformity with *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR).

*On behalf of the company*

  
Wang Dafei  
(Management Representative)

Place, Date of Issue: Shenzhen, May 20, 2022



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SRN: DE-AR-000000001

### Product Information:

Product name: Fully-auto chemiluminescence immunoassay analyzer  
Model: Maglumi 600  
Catalogue Number: 23020018  
Basic UDI-DI: 69471455M600Q7

### Intended purpose:

Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (b)

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.

We, Shenzhen New Industries Biomedical Engineering Co., Ltd, declare under the sole responsibility that the above listed device(s) is/are in conformity with *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR), and with the following EU legislation, which also require an EU Declaration of Conformity.

- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
- Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC

*On behalf of the company*

  
Wang Dafei  
(Management Representative)

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



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SRN: DE-AR-000000001

### Product Information:

Product name: Fully-auto chemiluminescence immunoassay analyzer  
Model: Maglumi 800  
Catalogue Number: 23020003  
Basic UDI-DI: 69471455M800QH

### Intended purpose:

Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (b)

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.

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*On behalf of the company*

  
Wang Dafei  
(Management Representative)

Place, Date of Issue: Shenzhen, Apr. 25, 2022



## EU Declaration of Conformity

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Tel: +49-40-2513175 Fax: +49-40-255726  
SRN: DE-AR-000000001

### Product Information:

Product name: Fully-auto chemiluminescence immunoassay analyzer  
Model: Maglumi 1000  
Catalogue Number: 23020009  
Basic UDI-DI: 69471455M1000H2

### Intended purpose:

Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (b)

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.

We, Shenzhen New Industries Biomedical Engineering Co., Ltd, declare under the sole responsibility that the above listed device(s) is/are in conformity with *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR), and with the following EU legislation, which also require an EU Declaration of Conformity.

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Wang Dafei  
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SRN: DE-AR-000000001

### Product Information:

Product name: Fully-auto chemiluminescence immunoassay analyzer  
Model: Maglumi 2000 Plus  
Catalogue Number: 23020007  
Basic UDI-DI: 69471455M2000PB3

### Intended purpose:

Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (b)

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.

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SRN: DE-AR-000000001

### Product Information:

Product name: Fully-auto chemiluminescence immunoassay analyzer  
Model: Maglumi 2000  
Catalogue Number: 23020006  
Basic UDI-DI: 69471455M2000H9

### Intended purpose:

Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (b)

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.

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SRN: DE-AR-000000001

### Product Information:

Product name: Fully-auto chemiluminescence immunoassay analyzer  
Model: Maglumi 4000 Plus  
Catalogue Number: 23020037  
Basic UDI-DI: 69471455M4000PBR

### Intended purpose:

Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (b)

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.

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SRN: DE-AR-000000001

### Product Information:

Product name: Fully-auto chemiluminescence immunoassay analyzer  
Model: Maglumi 4000  
Catalogue Number: 23020014  
Basic UDI-DI: 69471455M4000HP

### Intended purpose:

Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (b)

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SRN: DE-AR-000000001

### Product Information:

Product name: Reaction Cup  
Catalogue Number: 130105000101  
Basic UDI-DI: 69471455306W2

### Intended purpose:

The Reaction Cup is an IVD accessory intended to be used with the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (a)

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.

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SRN: DE-AR-000000001

### Product Information:

Product name: Reaction Module  
Catalogue Number: 630003  
Basic UDI-DI: 69471455301VQ

### Intended purpose:

The Reaction Module is an IVD accessory intended to be used with the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (a)

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.

We, Shenzhen New Industries Biomedical Engineering Co., Ltd, declare under the sole responsibility that the above listed device(s) is/are in conformity with *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR).

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### Product Information:

Product name: Starter 1+2  
Catalogue Number: 130299004M, 130299027M  
Basic UDI-DI: 69471455302VS

### Intended purpose:

The Starter 1+2 is for triggering chemiluminescence reaction to produce the light signal, and it is used in conjunction with MAGLUMI assay reagents on the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (a)

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.

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### Product Information:

Product name: System Tubing Cleaning Solution  
Catalogue Number: 130299007M  
Basic UDI-DI: 69471455305VY

### Intended purpose:

The System Tubing Cleaning Solution is used for the maintenance of the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (a)

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.

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SRN: DE-AR-000000001

**Product Information:**

Product name: Tip  
Catalogue Number: 130207000501  
Basic UDI-DI: 69471455307W4

**Intended purpose:**

The Tip is an IVD accessory intended to be used with the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (a)

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.

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SRN: DE-AR-000000001

**Product Information:**

Product name: Waste Bag  
Catalogue Number: 21060624, 21060625, 21060726  
Basic UDI-DI: 69471455322VY

**Intended purpose:**

The Waste Bag is used for collecting waste produced during the tests on MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (a)

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.

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Tel: +49-40-2513175 Fax: +49-40-255726  
SRN: DE-AR-000000001

### Product Information:

Product name: Waste Bag  
Catalogue Number: 130210000101, 130210000201  
Basic UDI-DI: 69471455322VY

### Intended purpose:

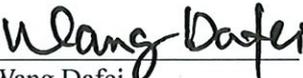
The Waste Bag is used for collecting waste produced during the tests on MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (a)

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Tel: +49-40-2513175 Fax: +49-40-255726  
SRN: DE-AR-000000001

### Product Information:

Product name: Fully-auto chemiluminescence immunoassay analyzer  
Model: MAGLUMI X3  
Catalogue Number: 010101003301  
Basic UDI-DI: 69471455X3G5

### Intended purpose:

Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (b)

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*On behalf of the company*

  
Wang Dafei  
(Management Representative)

Place, Date of Issue: Shenzhen, Apr. 25, 2022



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### 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  
SRN: CN-MF-000005655

### European Representative:

Shanghai International Holding Corp. GmbH (Europe)  
Eiffestrasse 80, 20537 Hamburg, Germany  
Tel: +49-40-2513175 Fax: +49-40-255726  
SRN: DE-AR-000000001

### Product Information:

Product name: Fully-auto chemiluminescence immunoassay analyzer  
Model: MAGLUMI X8  
Catalogue Number: 010101008801, 010101002101, 010101001901, 010101002301,  
010101002501  
Basic UDI-DI: 69471455X8GF

### Intended purpose:

Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (b)

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.

We, Shenzhen New Industries Biomedical Engineering Co., Ltd, declare under the sole responsibility that the above listed device(s) is/are in conformity with *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR), and with the following EU legislation, which also require an EU Declaration of Conformity.

- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
- Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC

*On behalf of the company*

  
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Wang Dafei

(Management Representative)

Place, Date of Issue: Shenzhen, Apr. 25, 2022



## EU Declaration of Conformity

In accordance with REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on *in vitro* diagnostic medical devices.

### Manufacturer:

Shenzhen New Industries Biomedical Engineering Co., Ltd.  
No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China  
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SRN: DE-AR-000000001

### Product Information:

Product name: Wash Concentrate  
Catalogue Number: 130299005M, 130299035M  
Basic UDI-DI: 69471455303VU

### Intended purpose:

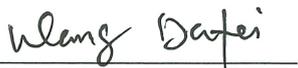
The Wash Concentrate is for the removal of substances which potentially interfere with the detection of signals, and it is used in conjunction with MAGLUMI assay reagents on the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (a)

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.

We, Shenzhen New Industries Biomedical Engineering Co., Ltd, declare under the sole responsibility that the above listed device(s) is/are in conformity with *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR).

*On behalf of the company*

  
Wang Dafei  
(Management Representative)

Place, Date of Issue: Shenzhen, June 20, 2022



## EU Declaration of Conformity

In accordance with REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on *in vitro* diagnostic medical devices.

### Manufacturer:

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### European Representative:

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Tel: +49-40-2513175 Fax: +49-40-255726  
SRN: DE-AR-000000001

### Product Information:

Product name: Sample Release Agent  
Catalogue Number: 130299026M  
Basic UDI-DI: 69471455320VU

### Intended purpose:

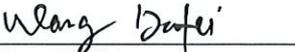
Sample Release Agent is an *in vitro* diagnostic reagent intended for the extraction of specific analytes from specimens. It is used together with specified immunoassays on the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (a)

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.

We, Shenzhen New Industries Biomedical Engineering Co., Ltd, declare under the sole responsibility that the above listed device(s) is/are in conformity with *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR).

*On behalf of the company*

  
Wang Dafei  
(Management Representative)

Place, Date of Issue: Shenzhen, June 20, 2022



## EU Declaration of Conformity

In accordance with REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on *in vitro* diagnostic medical devices.

### Manufacturer:

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### European Representative:

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Tel: +49-40-2513175 Fax: +49-40-255726  
SRN: DE-AR-000000001

### Product Information:

Product name: Sample Release Agent  
Catalogue Number: 130299034M  
Basic UDI-DI: 69471455325W6

### Intended purpose:

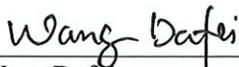
Sample Release Agent is an *in vitro* diagnostic reagent intended for the extraction of specific analytes from specimens. It is used together with specified immunoassays on the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System.

**Classification:** Class A, as per REGULATION (EU) 2017/746, Annex VIII, Rule 5 (a)

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.

We, Shenzhen New Industries Biomedical Engineering Co., Ltd, declare under the sole responsibility that the above listed device(s) is/are in conformity with *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR).

*On behalf of the company*

  
\_\_\_\_\_  
Wang Dafei  
(Management Representative)

Place, Date of Issue: Shenzhen, June 20, 2022