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
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SRN: DE-AR-000000001

Digitally signed by Bolea Petru
Date: 2023.01.05 14:16:54 EET
Reason: MoldSign Signature
Location: Moldova

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

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

EU Declaration of Conformity

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Manufacturer:
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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 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.

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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On behalf of the company

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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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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On behalf of the company

Wang Dafei
(Management Representative)

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

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)
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On behalf of the company

Wang Dafei
(Management Representative)

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

EU Declaration of Conformity

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Manufacturer:
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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 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.

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)
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On behalf of the company

Wang Dafei
(Management Representative)

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

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)
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On behalf of the company

Wang Dafei
(Management Representative)

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

EU Declaration of Conformity

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Manufacturer:
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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 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)

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

EU Declaration of Conformity

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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.

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

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

On behalf of the company

Wang Dafei
(Management Representative)

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

EU Declaration of Conformity

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SRN: DE-AR-000000001

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.

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: 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.

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

EU Declaration of Conformity

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Manufacturer:
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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.

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

EU Declaration of Conformity

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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.

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

EU Declaration of Conformity

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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)

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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Wang Dafei
(Management Representative)

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

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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)

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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Manufacturer:
Shenzhen New Industries Biomedical Engineering Co., Ltd.
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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 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

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
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: 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:
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: 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:
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: 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