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: +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 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.

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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