



## Declaration of Conformity

**Manufacturer:**

Shenzhen New Industries Biomedical Engineering Co., Ltd.  
No.16, Jinhui Road, Pingshan New District, Shenzhen, 518122, P.R. China  
Tel: + 86 755 26501514 Fax: + 86 755 26654850

**European Representative:**

Lotus Medical Equipment Limited  
26B Cameron Court, Cork Street, Dublin 8, Ireland  
Tel: + 00353-1-6571034 E-mail: peter@lotusme.org

**Product Name:**

(Product identifications see the attachment)

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

Others (Neither listed in List A or List B of Annex II, IVDD 98/79/EC, nor for self-testing)

**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 ISO 13485:2012 EN 980:2008 EN ISO 18113-1:2011 EN ISO 14971:2012  
EN ISO 18113-2:2011

**First Start of CE-MARK:** Oct 30, 2010

**Signature:** Managing Director

**Place, Date of Issue:** Shenzhen, Oct 20, 2015



Attachment

Item	Product Name	Cat.No
1	MAGLUMI Starter 1+2	130299004M
2	MAGLUMI Wash Concentrate	130299005M
3	MAGLUMI Reaction Modules	630003
4	MAGLUMI Light Check	130299006M
5	MAGLUMI System Tubing Cleaning Solution	130299007M
6	MAGLUMI Waste Bag	21060624
		21060625
		21060626
7	Alkaline Wash	1305990001
8	Acid Wash	1305990002
9	Hitergent	1305990003
10	ISE Cleaner	1305990004



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**European Representative:**

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26B Cameron Court, Cork Street, Dublin 8, Ireland  
Tel: + 00353-1-6571034 E-mail: peter@lotusme.org

**Product Name:**

MAGLUMI Fully-auto chemiluminescence immunoassay analyzer (Product identifications see the attachment)

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

Others (Neither listed in List A or List B of Annex II, IVDD 98/79/EC, nor for self-testing)

**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 ISO 14971: 2012	EN 61010-1: 2010	EN 62366:2008	EN 61326-1:2013
EN ISO 18113-1: 2011	EN 61010-2-101: 2002	EN 13612:2002	EN 61326-2-6:2013
EN ISO 18113-3: 2011	EN ISO 13485: 2012	EN 980:2008	

**First Start of CE-MARK:** May 20, 2012

**Signature:** Managing Director

**Place, Date of Issue:** Shenzhen, Oct 20, 2015



Attachment

Item	Model	Cat. No
1	Maglumi 600	23020018
2	Maglumi 800	23020003
3	Maglumi 1000	23020009
4	Maglumi 1000 Plus	23020020
5	Maglumi 2000	23020006
6	Maglumi 2000 Plus	23020007
7	Maglumi 4000	23020014



SJ-CE-270-007 V1

## 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:**

SARS-CoV-2 S-RBD IgG (CLIA) (Cat. No.: 130219017M, 130619017M)

**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 mentioned product meets 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:** July 16, 2020

**Signature:** General Director

**Place, Date of Issue:** Shenzhen, July 16, 2020