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:
See the attachment.

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

Conformity Assessment Route: Self-Declaration of Conformity, as per REGULATION (EU) 2017/746, Article 48 (10), first subparagraph

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
(Person Responsible for Regulatory Compliance)

Place, Date of Issue: Shenzhen, Aug. 26, 2024

Digitally signed by Ceaicovschi Tudor
Date: 2026.01.02 10:58:52 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Attachment-Product Information

Item	Product Name	Model	Catalogue No.	Basic UDI-DI	Intended purpose
1	Automatic Biochemistry Analyzer	Biossays 240	63000043	69471455B240MJ	Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.
2	Automatic Biochemistry Analyzer	Biossays 240 Plus	63000040	69471455B240PG2	Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.
3	Automatic Biochemistry Analyzer	BC1200	63000002	69471455BC1200AP	Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.
4	Automatic Biochemistry Analyzer	BC2200	63000004	69471455BC2200AW	Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.
5	Automatic Biochemistry Analyzer	Biolumi 8000	23010001	69471455BL8000EZ	Used in conjunction with a matched reagent for qualitative and/or quantitative analysis of the analytes in a human sample..
6	Automatic Biochemistry Analyzer	Biossays C8	010102008801; 010102002301; 010102002401; 010102002201; 010102002801; 010102004301	69471455C8EG	Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in a human sample.

7	Electrolyte analyzer	Biossays E6 Plus	010104000501; 010104000901	69471455E6P2W	The automatic electrolyte analyzer is used to analyze the content of electrolyte ions in human samples.
8	Electrolyte analyzer	Biossays E6	010104000301	69471455E6EJ	The automatic electrolyte analyzer is used to analyze the content of electrolyte ions in human samples.
9	Electrolyte Analyzer	E1200	63000009	69471455E1200EL	Apply the electrode method to detect the concentrations of potassium (K^+), sodium (Na^+), Chlorine (Cl^-), calcium (iCa^{2+}), pH value (power of hydrogen) in the human serum.
10	Fully-auto chemiluminescence immunoassay analyzer	Maglumi 600	23020018	69471455M600Q7	Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.
11	Fully-auto chemiluminescence immunoassay analyzer	Maglumi 800	23020003	69471455M800QH	Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.
12	Fully-auto chemiluminescence immunoassay analyzer	Maglumi 1000	23020009	69471455M1000H2	Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.
13	Fully-auto chemiluminescence immunoassay analyzer	Maglumi 2000 Plus	23020007	69471455M2000PB3	Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.

14	Fully-auto chemiluminescence immunoassay analyzer	Maglumi 2000	23020006	69471455M2000H9	Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.
15	Fully-auto chemiluminescence immunoassay analyzer	Maglumi 4000 Plus	23020037	69471455M4000PBR	Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.
16	Fully-auto chemiluminescence immunoassay analyzer	Maglumi 4000	23020014	69471455M4000HP	Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.
17	Fully-auto Nucleic Acid Purification System	Molecision MP-32	010109010101	69471455MP32UH	Used for extraction and purification of nucleic acid in clinical samples.
18	Fully-auto Nucleic Acid Purification System	Molecision MP-96	010109030101	69471455MP96VB	Used for extraction and purification of nucleic acid in clinical samples.
19	Fully-auto chemiluminescence immunoassay analyzer	MAGLUMI X3	010101003301	69471455X3G5	Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.
20	Fully-auto chemiluminescence immunoassay analyzer	MAGLUMI X6	010101006601; 010101006001; 010101006201; 010101006801; 010101006401; 010101007001	69471455X6GB	Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.

21	Fully-auto chemiluminescence immunoassay analyzer	MAGLUMI X8	010101008801, 010101002101, 010101001901, 010101002301, 010101002501	69471455X8GF	Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in the human sample.
22	Integrated System	Biolumi CX8	010108000901; 010108001101; 010108001301; 010108001501; 010108001701; 010108001901; 010108002101; 010108002301	69471455CX849	Used in conjunction with adapter reagents for qualitative and/or quantitative analysis of the analytes in a human sample.
23	Fully-auto Molecular Diagnostics System	Molecision R8	010109000101	69471455R8FV	Based on the magnetic bead method and real-time PCR techniques, the product is used with adapter reagent kit for qualitative and quantitative detection of target nucleic acids in test samples, by automatically completing a series of operations, including nucleic acid extraction, purification, amplification and detection.

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SRN: DE-AR-000000001

Product Information:
See the attachment.

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

Conformity Assessment Route: Self-Declaration of Conformity, as per REGULATION (EU) 2017/746, Article 48 (10), first subparagraph

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
(Person Responsible for Regulatory Compliance)

Place, Date of Issue: Shenzhen, Mar. 22, 2024

Attachment-Product Information

Item	Product Name	Specification	Catalogue No.	Basic UDI-DI	Intended purpose
1.	Reaction Module	6*64 reaction modules	630003	69471455301VQ	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.
2.	Reaction Cup	546 Cups/box	130105000101	69471455306W2	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.
3.	Tip	20×192 Tips	130208000201	69471455347WG	The Tip is an IVD accessory intended to be used with the MAGLUMI series Fully-auto Chemiluminescence Immunoassay Analyzer and Biolumi series Integrated System.
4.	Starter 1+2	Starter 1: 1×230 mL; Starter 2: 1×230 mL	130299004M	69471455302VS	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.
		Starter 1: 1×1.5 L; Starter 2: 1×1.5 L	130299027M		
5.	Wash Concentrate	1×714 mL	130299005M	69471455303VU	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.
		1×10 L	130299035M		
6.	System Tubing Cleaning Solution	1×500 mL	130299007M	69471455305VY	The System Tubing Cleaning Solution is used for the maintenance of the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System.
7.	Light Check	5×2 mL	130299006M	69471455314VZ	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.
8.	Sample Diluent	1×25 mL	130299039M	69471455345WC	Sample Diluent is used as a sample diluent in conjunction with MAGLUMI assays on the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System.
9.	Sample Diluent	1×25 mL	130299038M	69471455344WA	Sample Diluent is used as a sample diluent in conjunction with MAGLUMI assays on the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System.
10.	Sample Diluent	1×25 mL	130299037M	69471455343W8	Sample Diluent is used as a sample diluent in conjunction with MAGLUMI assays on the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System.
11.	Sample Diluent	1×25 mL	130299036M	69471455342W6	Sample Diluent is used as a sample diluent in conjunction with MAGLUMI assays on the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System.
12.	Sample Release Agent	4×0.2 g	130299026M	69471455320VU	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.
13.	Sample Extraction Solution	1×100 mL	130299033M	69471455323W2	Sample Extraction Solution 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
		100×1.0 mL	130299032M		
		50×1.0 mL	130299031M		
		25×1.0 mL	130299030M		

					Integrated System.
14.	Sample Release Agent	Sample Release Agent 1: 1×25 mL; Sample Release Agent 2: 1×25 mL	130299034M	69471455325W6	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.
15.	Waste Bag	50 pieces/box (220×210×195 mm)	21060624	69471455322VY	The Waste Bag is used for collecting waste produced during the tests on MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer.
		50 pieces/box (180×136×205 mm)	21060625		
		50 pieces/box (180×138×150 mm)	21060726		
		50 pieces/box (720×420mm)	130210000201		The Waste Bag is used for collecting waste produced during the tests on MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer, Biolumi series Integrated System, Decapper Module, Molecision series Fully auto Molecular Diagnostics System and Hemolumi series Automated coagulation analyzer.
		50 pieces/box (520×310mm)	130210000101		
		50 pieces/box (900mm×1000mm)	130210000901		
		40 pieces/box (630×330mm)	750105000801		
		30 pieces/box (740×540mm)	750105000301		
		40 pieces/box (380×430mm)	750105000601		
16.	Alkaline Wash	1×2000 g	1305990001	69471455309W8	Alkaline Wash is used to wash the carryover contamination of reagent probes, sample probes and cuvettes on Biossays series Automatic Biochemistry Analyzer and Biolumi series Integrated System.
		2×60 g	1305990010		
		2×40 g	1305990011		
17.	Acid Wash	1×2000 g	1305990006	69471455310VR	Acid Wash is used to wash carryover contamination of the reagent probes, sample probes and cuvettes on Biossays series Automatic Biochemistry Analyzer and Biolumi series Integrated System.
		1×500 g	1305990002		
		2×60 g	1305990008		
		2×40 g	1305990007		
18.	ISE Cleaner	1×20 mL	1305990004	69471455312VV	ISE Cleaner is used to wash and maintain the ISE units of Biossays series Automatic Biochemistry Analyzer, Biolumi series Integrated System, and also wash and maintenance the Electrolyte Analyzer.
19.	Nucleic Acid	32 Isolations/kit	132131001HC	69471455326W8	The Nucleic Acid Extraction Kit is intended for

	Extraction Kit				isolating nucleic acids (NA) from sample materials by using the Fully-auto Nucleic Acid Purification System for an in vitro testing.
20.	Nucleic Acid Extraction Kit	32 Isolations/kit	132131015HC	69471455348WJ	The Nucleic Acid Extraction Kit is intended for isolating nucleic acids (NA) from sample materials by using the Fully-auto Nucleic Acid Purification System for an in vitro testing.
21.	96-Well Deep-Well Plate	10×5 Plates	750101000101	694714553503JR	The 96-Well Deep-Well Plate is an IVD accessory intended to be used with the Molecision series Fully auto Molecular Diagnostics System. It serves as a container for nucleic acid extraction and detection processes.
22.	PCR Plate	15×10 Plates	750101000301	694714553504JT	The PCR Plate is an IVD accessory intended to be used with the Molecision series Fully-auto Molecular Diagnostics System. It serves as a reactor in the nucleic acid detection process.
23.	Sleeve	36 × 96 Sleeves	750103000401	694714553505JV	The Sleeve is an IVD accessory intended to be used with the Molecision series Fully-auto Molecular Diagnostics System. It is used to assist the extraction of nucleic acid.
24.	Tip	36 × 96 Tips	750103000501	694714553506JX	The Tip is an IVD accessory intended to be used with the Molecision series Fully-auto Molecular Diagnostics System. It is used to transfer samples and reagents.
25.	Tubing Cleaning Solution	1×1.9 L	132131018H1A	694714553507JZ	The Tubing Cleaning Solution is used in conjunction with the Fully-Auto Molecular Diagnostics System Molecision R8 to maintain the Fully-Auto Molecular Diagnostics System Molecision R8 by taking advantage of the fact that sodium azide, the main component of the Tubing Cleaning Solution, can dissolve proteins.
26.	Magnetic Glass Particles	1×25 mL	132131012H2A	69471455340W2	Used in conjunction with companion nucleic acid extraction or purification reagents for sample preparation, it is designed to bind to nucleic acids
		2×25 mL	132131012H1A		

					released from samples after the addition of proteases and lysis reagents during the sample preparation process. It is not directly involved in the assay itself.
27.	Wash Buffer	1×26 mL	132131011H1A	69471455339WH	For cleaning of the reaction system during the assay process to facilitate in vitro detection of the substance to be tested, is not a separate cleaning solution for instrument cleaning.
		2×26 mL	132131011H2A		
28.	Wash Buffer	1×450 mL	132131010H1A	69471455338WF	For cleaning of the reaction system during the assay process to facilitate in vitro detection of the substance to be tested, is not a separate cleaning solution for instrument cleaning.
29.	Wash Buffer	1×450 mL	132131009H1A	69471455337WD	For cleaning of the reaction system during the assay process to facilitate in vitro detection of the substance to be tested, is not a separate cleaning solution for instrument cleaning.
30.	Wash Buffer	1×450 mL	132131008H1A	69471455336WB	For cleaning of the reaction system during the assay process to facilitate in vitro detection of the substance to be tested, is not a separate cleaning solution for instrument cleaning.
31.	Lysis Buffer	1×450 mL	132131007H1A	69471455335W9	Used in the pretreatment of samples to be tested to release the substance to be tested in the sample from its state of binding to other substances. To facilitate the detection of the substance to be tested using in vitro diagnostic reagents or instruments.
32.	Proteinase K	1×4.2 mL	132131006H1A	69471455334W7	Used in conjunction with a companion nucleic acid extraction or purification reagent to extract nucleic acids from the sample to be tested in order to facilitate the detection of the test substance using an in vitro diagnostic reagent or instrument. It is not directly involved in the assay itself.

EU Declaration of Conformity

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SRN: DE-AR-000000001

Product/Product line: See the attachment
Basic UDI-DI: See the attachment

Intended purpose: See the attachment

Classification (IVDR, Annex VIII): See the attachment

Conformity Assessment Route: Annex IX Chapters I and III
We herewith declare that the EU declaration of conformity is issued under the sole responsibility of the manufacturer. The products mentioned above are in conformity with the *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR). All supporting documentations are retained under the premises of the manufacturer.

Notified Body: TÜV SÜD Product Service GmbH
NB Identification Number: 0123
EU QM Certificate No.: V12 105113 0005 Rev. 03

Signature: Wang Dafei

Name: Wang Dafei

Position: Person Responsible for Regulatory Compliance

Place, Date of Issue: Shenzhen, Sept. 11, 2025

Attachment

Item	Product name	Catalogue No.	Basic UDI-DI	Intended purpose	Classification
1	AFP (CLIA)	130201033M; 130601033M; 130701033M	69471455220VP	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of AFP in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of hepatocellular carcinoma (HCC).	Class C
2	AFP (CLIA) Controls	160201220MT	69471455220VP	The AFP controls are intended for performing quality control procedures with MAGLUMI AFP assay when used for the quantitative determination of AFP in human serum and plasma.	Class C
3	CEA (CLIA)	130201032M; 130601032M; 130701032M	69471455219W6	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of CEA in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the management of cancer patients.	Class C
4	CEA (CLIA) Controls	160201219MT	69471455219W6	The CEA controls are intended for performing quality control procedures with MAGLUMI CEA assay when used for the quantitative determination of CEA in human serum and plasma.	Class C
5	CA 50 (CLIA)	130201036M; 130601036M; 130701036M	69471455223VV	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of CA 50 in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the management of gastrointestinal malignancies.	Class C
6	CA 50 (CLIA) Controls	160201223MT	69471455223VV	The CA 50 controls are intended for performing quality control procedures with MAGLUMI CA 50 assay when used for the quantitative determination of CA 50 in human serum and plasma.	Class C
7	CA 242 (CLIA)	130201039M; 130601039M; 130701039M	69471455226W3	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of CA 242 in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the management of gastrointestinal malignancies (pancreatic cancer and colorectal cancers, etc.).	Class C
8	CA 242 (CLIA) Controls	160201226MT	69471455226W3	The CA 242 controls are intended for performing quality control procedures with MAGLUMI CA 242 assay when	Class C

				used for the quantitative determination of CA 242 in human serum and plasma.	
9	CA 125 (CLIA)	130201031M; 130601031M; 130701031M	69471455218W4	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of CA 125 in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the management of ovarian cancer.	Class C
10	CA 125 (CLIA) Controls	160201218MT	69471455218W4	The CA 125 controls are intended for performing quality control procedures with MAGLUMI CA 125 assay when used for the quantitative determination of CA 125 in human serum and plasma.	Class C
11	CA 72-4 (CLIA)	130201042M; 130601042M; 130701042M	69471455229W9	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of CA 72-4 in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the therapeutic monitoring of carcinomas of the stomach and ovaries.	Class C
12	CA 72-4 (CLIA) Controls	160201229MT	69471455229W9	The CA 72-4 controls are intended for performing quality control procedures with MAGLUMI CA 72-4 assay when used for the quantitative determination of CA 72-4 in human serum and plasma.	Class C
13	CA 15-3 (CLIA)	130201038M; 130601038M; 130701038M	69471455225VZ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of CA 15-3 in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the management of breast carcinoma.	Class C
14	CA 15-3 (CLIA) Controls	160201225MT	69471455225VZ	The CA 15-3 controls are intended for performing quality control procedures with MAGLUMI CA 15-3 assay when used for the quantitative determination of CA 15-3 in human serum and plasma.	Class C
15	CYFRA 21-1 (CLIA)	130201040M; 130601040M; 130701040M	69471455227W5	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of CYFRA 21-1 in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in managing the course of non-small cell lung cancer.	Class C
16	CYFRA 21-1 (CLIA) Controls	160201227MT	69471455227W5	The CYFRA 21-1 controls are intended for performing quality control procedures with MAGLUMI CYFRA 21-1 assay when used for the	Class C

				quantitative determination of CYFRA 21-1 in human serum and plasma.	
17	SCCA (CLIA)	130201041M; 130601041M; 130701041M	69471455228W7	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of SCCA in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the management of patients with squamous cell carcinoma.	Class C
18	SCCA (CLIA) Controls	160201228MT	69471455228W7	The SCCA controls are intended for performing quality control procedures with MAGLUMI SCCA assay when used for the quantitative determination of SCCA in human serum and plasma.	Class C
19	NSE (CLIA)	130201030M; 130601030M; 130701030M	69471455217W2	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of NSE in human serum using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the management of patients with tumor diseases, particularly small cell lung cancer (SCLC) and neuroblastoma.	Class C
20	NSE (CLIA) Controls	160201217MT	69471455217W2	The NSE controls are intended for performing quality control procedures with MAGLUMI NSE assay when used for the quantitative determination of NSE in human serum.	Class C
21	Total PSA (CLIA)	130201034M; 130601034M; 130701034M	69471455221VR	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Total PSA (tPSA) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the management of patients with prostate cancer.	Class C
22	Total PSA (CLIA) Controls	160201221MT	69471455221VR	The Total PSA controls are intended for performing quality control procedures with MAGLUMI Total PSA assay when used for the quantitative determination of Total PSA (tPSA) in human serum and plasma.	Class C
23	Free PSA (CLIA)	130201035M; 130601035M; 130701035M	69471455222VT	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Free PSA (fPSA) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in distinguishing prostate cancer from benign prostatic conditions with MAGLUMI Total PSA value in the	Class C

				range 4.00 ng/mL to 10.0 ng/mL.	
24	Free PSA (CLIA) Controls	160201222MT	69471455222VT	The Free PSA controls are intended for performing quality control procedures with MAGLUMI Free PSA assay when used for the quantitative determination of Free PSA (fPSA) in human serum and plasma.	Class C
25	PIVKA-II (CLIA)	130201029M; 130601029M; 130701029M	69471455150VT	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of PIVKA-II in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in diagnosis of HCC (hepato-cellular carcinoma), monitoring of high risk patients (hepatitis or cirrhosis, etc.) for development of HCC, and in management of HCC.	Class C
26	PIVKA-II (CLIA) Controls	160201150MT	69471455150VT	The PIVKA-II controls are intended for performing quality control procedures with MAGLUMI PIVKA-II assay when used for the quantitative determination of PIVKA-II in human serum and plasma.	Class C
27	ProGRP (CLIA)	130201523M; 130601523M; 130701523M	69471455420VZ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of ProGRP in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the differential diagnosis in lung cancer and in management of patients with small cell lung cancer in conjunction with other clinical methods.	Class C
28	ProGRP (CLIA) Controls	160201420MT	69471455420VZ	The ProGRP controls are intended for performing quality control procedures with MAGLUMI ProGRP assay when used for the quantitative determination of ProGRP in human serum and plasma.	Class C
29	HE4 (CLIA)	130201525M; 130601525M; 130701525M	69471455421W3	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of HE4 in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in monitoring recurrence or progressive disease in patients with ovarian cancer. Serial testing for patient HE4 values should be used in conjunction with other clinical findings used for monitoring ovarian cancer.	Class C
30	HE4 (CLIA) Controls	160201421MT	69471455421W3	The HE4 controls are intended for performing quality control procedures with MAGLUMI HE4 assay when used	Class C

				for the quantitative determination of HE4 in human serum and plasma.	
31	HER-2 (CLIA)	130201526M; 130601526M; 130701526M	69471455422W5	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of HER-2 in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System. The HER-2 assay may be used in the follow-up and monitoring of patients with metastatic breast cancer whose initial serum HER-2 level is great than the expected value. HER-2 values should be used in conjunction with information available from clinical and other diagnostic procedures in the management of breast cancer.	Class C
32	HER-2 (CLIA) Controls	160201422MT	69471455422W5	The HER-2 controls are intended for performing quality control procedures with MAGLUMI HER-2 assay when used for the quantitative determination of HER-2 in human serum and plasma.	Class C
33	S100 (CLIA)	130251017M; 130651017M; 130751017M	69471455296WQ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of S100 in human serum using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the management of patients suffering from malignant melanoma.	Class C
34	S100 (CLIA) Controls	160201296MT	69471455296WQ	The S100 controls are intended for performing quality control procedures with MAGLUMI S100 assay when used for the quantitative determination of S100 in human serum.	Class C
35	Anti-Sm/RNP IgG (CLIA)	130217511M; 130617511M; 130717511M	69471455410VW	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of IgG antibodies to Sm/RNP (Anti-Sm/RNP IgG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Mixed Connective Tissue Disease (MCTD) and Systemic Lupus Erythematous (SLE).	Class B
36	Anti-Sm/RNP IgG (CLIA) Controls	160201410MT	69471455410VW	The Anti-Sm/RNP IgG controls are intended for performing quality control procedures with MAGLUMI Anti-Sm/RNP IgG assay when used for the quantitative determination of Anti-Sm/RNP IgG in human serum and plasma.	Class B
37	Anti-Scl-70	130217505M;	69471455415W8	The kit is an in vitro chemiluminescence	Class

	IgG (CLIA)	130617505M; 130717505M		immunoassay for the quantitative determination of IgG antibodies to Scl-70 (Anti-Scl-70 IgG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Systemic Sclerosis (SSc).	B
38	Anti-Scl-70 IgG (CLIA) Controls	160201415MT	69471455415W8	The Anti-Scl-70 IgG controls are intended for performing quality control procedures with MAGLUMI Anti-Scl-70 IgG assay when used for the quantitative determination of Anti-Scl-70 IgG in human serum and plasma.	Class B
39	Anti-SS-A/Ro IgG (CLIA)	130217513M; 130617513M; 130717513M	69471455412W2	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of IgG antibodies to SS-A/Ro (Anti-SS-A/Ro IgG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Sjögren's Syndrome (SS) and Systemic Lupus Erythematous (SLE).	Class B
40	Anti-SS-A/Ro IgG (CLIA) Controls	160201412MT	69471455412W2	The Anti-SS-A/Ro IgG controls are intended for performing quality control procedures with MAGLUMI Anti-SS-A/Ro IgG assay when used for the quantitative determination of Anti-SS-A/Ro IgG in human serum and plasma.	Class B
41	ENA Screen (CLIA)	130217504M; 130617504M; 130717504M	69471455406W7	The kit is an in vitro chemiluminescence immunoassay for the semi-quantitative determination of IgG class antibodies to extractable nuclear antigens (ENA) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed multiple systemic autoimmune diseases (Systemic Lupus Erythematosus (SLE), Mixed Connective Tissue Disease (MCTD), Sjögren's Syndrome (SS), Systemic Sclerosis (SSc) and Polymyositis/Dermatomyositis (PM/DM)).	Class B
42	ENA Screen (CLIA) Controls	160201406MT	69471455406W7	The ENA Screen controls are intended for performing quality control procedures with MAGLUMI ENA Screen assay when used for the semi-quantitative determination of ENA Screen in human serum and plasma.	Class B

43	AMA-M2 IgG (CLIA)	130217507M; 130617507M; 130717507M	69471455417WC	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of IgG antibodies to Mitochondrial M2 antigen (AMA-M2 IgG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Primary Biliary Cirrhosis (PBC).	Class B
44	AMA-M2 IgG (CLIA) Controls	160201417MT	69471455417WC	The AMA-M2 IgG controls are intended for performing quality control procedures with MAGLUMI AMA-M2 IgG assay when used for the quantitative determination of AMA-M2 IgG in human serum and plasma.	Class B
45	Anti-Histones IgG (CLIA)	130217508M; 130617508M; 130717508M	69471455408WB	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of IgG antibodies to Histones (Anti-Histones IgG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Systemic Lupus Erythematous (SLE) and Drug-induced Lupus (DIL).	Class B
46	Anti-Histones IgG (CLIA) Controls	160201408MT	69471455408WB	The Anti-Histones IgG controls are intended for performing quality control procedures with MAGLUMI Anti-Histones IgG assay when used for the quantitative determination of Anti-Histones IgG in human serum and plasma.	Class B
47	Anti-Sm IgG (CLIA)	130217512M; 130617512M; 130717512M	69471455411VY	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of IgG antibodies to Sm (Anti-Sm IgG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Systemic Lupus Erythematous (SLE).	Class B
48	Anti-Sm IgG (CLIA) Controls	160201411MT	69471455411VY	The Anti-Sm IgG controls are intended for performing quality control procedures with MAGLUMI Anti-Sm IgG assay when used for the quantitative determination of Anti-Sm IgG in human serum and plasma.	Class B
49	Anti-Centromeres IgG (CLIA)	130217506M; 130617506M; 130717506M	69471455416WA	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of IgG antibodies to centromeres (Anti-Centromeres IgG) in	Class B

				human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed limited cutaneous Systemic Sclerosis (lcSSc).	
50	Anti-Centromeres IgG (CLIA) Controls	160201416MT	69471455416WA	The Anti-Centromeres IgG controls are intended for performing quality control procedures with MAGLUMI Anti-Centromeres IgG assay when used for the quantitative determination of Anti-Centromeres IgG in human serum and plasma.	Class B
51	Anti-Rib-P IgG (CLIA)	130217510M; 130617510M; 130717510M	69471455409WD	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of IgG antibodies to Rib-P (Anti-Rib-P IgG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Systemic Lupus Erythematous (SLE).	Class B
52	Anti-Rib-P IgG (CLIA) Controls	160201409MT	69471455409WD	The Anti-Rib-P IgG controls are intended for performing quality control procedures with MAGLUMI Anti-Rib-P IgG assay when used for the quantitative determination of Anti-Rib-P IgG in human serum and plasma.	Class B
53	ANA Screen (CLIA)	130217503M; 130617503M; 130717503M	69471455405W5	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of IgG class antinuclear antibodies (ANA) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed multiple systemic autoimmune diseases (Systemic Lupus Erythematosus (SLE), Mixed Connective Tissue Disease (MCTD), Sjögren's Syndrome (SS), Systemic Sclerosis (SSc), Polymyositis/Dermatomyositis (PM/DM), Primary Biliary Cirrhosis (PBC)).	Class B
54	ANA Screen (CLIA) Controls	160201405MT	69471455405W5	The ANA Screen controls are intended for performing quality control procedures with MAGLUMI ANA Screen assay when used for the quantitative determination of ANA Screen in human serum and plasma.	Class B
55	Anti-dsDNA IgG (CLIA)	130217502M; 130617502M;	69471455407W9	The kit is an in vitro chemiluminescence immunoassay for the quantitative	Class B

		130717502M		determination of IgG antibodies to double-stranded DNA (Anti-dsDNA IgG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Systemic Lupus Erythematous (SLE) and monitoring disease progress in patients.	
56	Anti-dsDNA IgG (CLIA) Controls	160201407MT	69471455407W9	The Anti-dsDNA IgG controls are intended for performing quality control procedures with MAGLUMI Anti-dsDNA IgG assay when used for the quantitative determination of Anti-dsDNA IgG in human serum and plasma.	Class B
57	Anti-CCP (CLIA)	130217501M; 130617501M; 130717501M	69471455404W3	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of IgG antibodies to cyclic citrullinated peptides (Anti-CCP) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Rheumatoid Arthritis (RA).	Class B
58	Anti-CCP (CLIA) Controls	160201404MT	69471455404W3	The Anti-CCP controls are intended for performing quality control procedures with MAGLUMI Anti-CCP assay when used for the quantitative determination of Anti-CCP in human serum and plasma.	Class B
59	Anti-SS-B IgG (CLIA)	130217514M; 130617514M; 130717514M	69471455413W4	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of IgG antibodies to SS-B (Anti-SS-B IgG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Sjögren's Syndrome (SS) and Systemic Lupus Erythematous (SLE).	Class B
60	Anti-SS-B IgG (CLIA) Controls	160201413MT	69471455413W4	The Anti-SS-B IgG controls are intended for performing quality control procedures with MAGLUMI Anti-SS-B IgG assay when used for the quantitative determination of Anti-SS-B IgG in human serum and plasma.	Class B
61	Anti-Jo-1 IgG (CLIA)	130217509M; 130617509M; 130717509M	69471455414W6	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of IgG antibodies to Jo-1 (Anti-Jo-1 IgG) in human serum and	Class B

				plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Polymyositis/Dermatomyositis (PM/DM).	
62	Anti-Jo-1 IgG (CLIA) Controls	160201414MT	69471455414W6	The Anti-Jo-1 IgG controls are intended for performing quality control procedures with MAGLUMI Anti-Jo-1 IgG assay when used for the quantitative determination of Anti-Jo-1 IgG in human serum and plasma.	Class B
63	Anti-MPO IgG (CLIA)	130217015M; 130617015M; 130717015M	69471455188WL	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of anti-myeloperoxidase IgG (Anti-MPO IgG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Intergrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed ANCA associated vasculitis.	Class B
64	Anti-MPO IgG (CLIA) Controls	160201188MT	69471455188WL	The Anti-MPO IgG controls are intended for performing quality control procedures with MAGLUMI Anti-MPO IgG assay when used for the quantitative determination of Anti-MPO IgG in human serum and plasma.	Class B
65	cTnI (CLIA)	130256002M; 130656002M; 130756002M	69471455292WG	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of cardiac troponin I (cTnI) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed myocardial infarction.	Class C
66	cTnI (CLIA) Controls	160201292MT	69471455292WG	The cTnI controls are intended for performing quality control procedures with MAGLUMI cTnI assay when used for the quantitative determination of cTnI in human serum and plasma.	Class C
67	H. pylori IgG (CLIA)	130201521M; 130601521M; 130701521M	69471455430W4	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of H. pylori IgG in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of H. pylori infection in persons.	Class B
68	H. pylori IgG (CLIA)	160201430MT	69471455430W4	The H. pylori IgG controls are intended for performing quality control	Class B

	Controls			procedures with MAGLUMI H. pylori IgG assay when used for the qualitative determination of H. pylori IgG in human serum and plasma.	
69	BNP (CLIA)	130206516M; 130606516M; 130706516M	69471455425WB	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of BNP in human plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and assessment of the severity of heart failure.	Class C
70	BNP (CLIA) Controls	160201425MT	69471455425WB	The BNP controls are intended for performing quality control procedures with MAGLUMI BNP assay when used for the quantitative determination of BNP in human plasma.	Class C
71	Gastrin-17 (CLIA)	130201522M; 130601522M; 130701522M	69471455426WD	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Gastrin-17 in human serum using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed the atrophic gastritis.	Class B
72	Gastrin-17 (CLIA) Controls	160201426MT	69471455426WD	The Gastrin-17 controls are intended for performing quality control procedures with MAGLUMI Gastrin-17 assay when used for the quantitative determination of Gastrin-17 in human serum.	Class B
73	Lp-PLA2 (CLIA)	130206515M; 130606515M; 130706515M	69471455419WG	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of lipoprotein-associated phospholipase A2 (Lp-PLA2) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for monitoring the degree of patients with atherosclerosis inflammation, and an aid in the diagnosis of individuals with suspected or confirmed coronary heart disease and ischemic stroke caused by atherosclerosis.	Class C
74	Lp-PLA2 (CLIA) Controls	160201419MT	69471455419WG	The Lp-PLA2 controls are intended for performing quality control procedures with MAGLUMI Lp-PLA2 assay when used for the quantitative determination of Lp-PLA2 in human serum and plasma.	Class C
75	H-FABP (CLIA)	130206512M; 130606512M; 130706512M	69471455418WE	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of heart-type fatty acid binding protein (H-FABP) in human	Class C

				serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed acute myocardial infarction.	
76	H-FABP (CLIA) Controls	160201418MT	69471455418WE	The H-FABP controls are intended for performing quality control procedures with MAGLUMI H-FABP assay when used for the quantitative determination of H-FABP in human serum and plasma.	Class C
77	FA (CLIA)	130263001M; 130663001M; 130763001M	69471455216VY	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Folate (FA) in human serum, plasma and red blood cells using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System. Folate measurements are used for an aid in the diagnosis and treatment of individuals with suspected or confirmed anemias.	Class B
78	FA (CLIA) Controls	160201216MT	69471455216VY	The FA controls are intended for performing quality control procedures with MAGLUMI FA assay when used for the quantitative determination of Folate (FA) in human serum, plasma and red blood cells.	Class B
79	IL-6 (CLIA)	130216504M; 130616504M; 130716504M	69471455424W9	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of IL-6 in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay can be used to aid in the management of critically ill patients as early indicator for acute inflammation.	Class C
80	IL-6 (CLIA) Controls	160201424MT	69471455424W9	The IL-6 controls are intended for performing quality control procedures with MAGLUMI IL-6 assay when used for the quantitative determination of IL-6 in human serum and plasma.	Class C
81	Aldosterone (CLIA)	130256007M; 130656007M; 130756007M	69471455295WN	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Aldosterone (ALD) in human serum, plasma and urine using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and treatment of individuals with suspected or confirmed primary aldosteronism (a disorder caused by the excessive secretion of aldosterone by the adrenal gland), hypertension caused by primary	Class B

				aldosteronism, selective hypoaldosteronism, edematous states, and other conditions of electrolyte imbalance.	
82	Aldosterone (CLIA) Controls	160201295MT	69471455295WN	The Aldosterone controls are intended for performing quality control procedures with MAGLUMI Aldosterone assay when used for the quantitative determination of Aldosterone in human serum, plasma and urine.	Class B
83	Direct Renin (CLIA)	130206511M; 130606511M; 130706511M	69471455428WH	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Direct Renin in human plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and treatment of a number of hypertension types in humans.	Class B
84	Direct Renin (CLIA) Controls	160201428MT	69471455428WH	The Direct Renin controls are intended for performing quality control procedures with MAGLUMI Direct Renin assay when used for the quantitative determination of Direct Renin in human plasma.	Class B
85	IGFBP-3 (CLIA)	130298505M; 130698505M; 130798505M	69471455429WK	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of IGFBP-3 in human serum using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the evaluation of individuals with suspected or confirmed growth disorders.	Class B
86	IGFBP-3 (CLIA) Controls	160201429MT	69471455429WK	The IGFBP-3 controls are intended for performing quality control procedures with MAGLUMI IGFBP-3 assay when used for the quantitative determination of IGFBP-3 in human serum.	Class B
87	Serum Amyloid A (CLIA)	130216005M; 130616005M; 130716005M	69471455177WF	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Serum Amyloid A (SAA) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay can be used as a non-specific inflammatory indicator.	Class B
88	Serum Amyloid A (CLIA) Controls	160201177MT	69471455177WF	The Serum Amyloid A controls are intended for performing quality control procedures with MAGLUMI Serum Amyloid A assay when used for the quantitative determination of Serum Amyloid A (SAA) in human serum and plasma.	Class B

89	EPO (CLIA)	130213003M; 130613003M; 130713003M	69471455179WK	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Erythropoietin (EPO) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed anemias and polycythemias.	Class B
90	EPO (CLIA) Controls	160201179MT	69471455179WK	The EPO controls are intended for performing quality control procedures with MAGLUMI EPO assay when used for the quantitative determination of EPO in human serum and plasma.	Class B
91	Ferritin (CLIA)	130251001M; 130651001M; 130751001M	69471455263W9	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Ferritin in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload), iron deficiency amemia and hepatocellular carcinoma.	Class C
92	Ferritin (CLIA) Controls	160201263MT	69471455263W9	The Ferritin controls are intended for performing quality control procedures with MAGLUMI Ferritin assay when used for the quantitative determination of Ferritin in human serum and plasma.	Class C
93	TRAb (CLIA)	130253009M; 130653009M; 130753009M	69471455290WC	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of TSH receptor antibodies (TRAb) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Graves' disease.	Class B
94	TRAb (CLIA) Controls	160201290MT	69471455290WC	The TRAb controls are intended for performing quality control procedures with MAGLUMI TRAb assay when used for the quantitative determination of TRAb in human serum and plasma.	Class B
95	Anti-IA2 (CLIA)	130205508M; 130605508M; 130705508M	69471455431W6	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of tyrosine phosphatase-related islet antigen 2 antibody (anti-IA2) in human serum using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid	Class B

				in the diagnosis of individuals with suspected or confirmed Type 1 diabetes mellitus (T1DM).	
96	Anti-IA2 (CLIA) Controls	160201431MT	69471455431W6	The Anti-IA2 controls are intended for performing quality control procedures with MAGLUMI Anti-IA2 assay when used for the quantitative determination of Anti-IA2 in human serum.	Class B
97	ICA (CLIA)	130205506M; 130605506M; 130705506M	69471455432W8	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of islet cell antibody (ICA) in human serum using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed type 1 diabetes mellitus (T1DM).	Class B
98	ICA (CLIA) Controls	160201432MT	69471455432W8	The ICA controls are intended for performing quality control procedures with MAGLUMI ICA assay when used for the quantitative determination of islet cell antibody (ICA) in human serum.	Class B
99	Free T4 (CLIA)	130253004M; 130653004M; 130753004M	69471455245W7	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of free thyroxine (Free T4) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in diagnosis and treatment of individuals with suspected or confirmed thyroid diseases.	Class B
100	Free T4 (CLIA) Controls	160201245MT	69471455245W7	The Free T4 controls are intended for performing quality control procedures with MAGLUMI Free T4 assay when used for the quantitative determination of Free T4 in human serum and plasma.	Class B
101	Total T3 (CLIA)	130253003M; 130653003M; 130753003M	69471455242VZ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of total triiodothyronine (Total T3) in human serum and plasma using the MAGLUMI series Fully-auto Chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in diagnosis and treatment of individuals with suspected or confirmed thyroid diseases such as hyperthyroidism.	Class B
102	Total T3 (CLIA) Controls	160201242MT	69471455242VZ	The Total T3 controls are intended for performing quality control procedures with MAGLUMI Total T3 assay when used for the quantitative determination of Total T3 in human serum and plasma.	Class B
103	Total T4 (CLIA)	130253002M; 130653002M;	69471455243W3	The kit is an in vitro chemiluminescence immunoassay for the quantitative	Class B

		130753002M		determination of total thyroxine (Total T4) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in diagnosis and treatment of individuals with suspected or confirmed thyroid diseases.	
104	Total T4 (CLIA) Controls	160201243MT	69471455243W3	The Total T4 controls are intended for performing quality control procedures with MAGLUMI Total T4 assay when used for the quantitative determination of Total T4 in human serum and plasma.	Class B
105	Free T3 (CLIA)	130253005M; 130653005M; 130753005M	69471455244W5	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of free triiodothyronine (Free T3) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in diagnosis and treatment of individuals with suspected or confirmed thyroid diseases such as hyperthyroidism.	Class B
106	Free T3 (CLIA) Controls	160201244MT	69471455244W5	The Free T3 controls are intended for performing quality control procedures with MAGLUMI Free T3 assay when used for the quantitative determination of Free T3 in human serum and plasma.	Class B
107	Rev T3 (CLIA)	130253010M; 130653010M; 130753010M	69471455246W9	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Rev T3 (rT3) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and treatment of individuals with suspected or confirmed thyroid diseases.	Class B
108	Rev T3 (CLIA) Controls	160201246MT	69471455246W9	The Rev T3 controls are intended for performing quality control procedures with MAGLUMI Rev T3 assay when used for the quantitative determination of Rev T3 in human serum and plasma.	Class B
109	Anti-Tg (CLIA)	130253007M; 130653007M; 130753007M	69471455247WB	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-Tg in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed certain thyroid disorders.	Class B
110	Anti-Tg (CLIA) Controls	160201247MT	69471455247WB	The Anti-Tg controls are intended for performing quality control procedures with MAGLUMI Anti-Tg assay when	Class B

				used for the quantitative determination of Anti-Tg in human serum and plasma.	
111	Anti-TM (CLIA)	130253008M; 130653008M; 130753008M	69471455248WD	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-TM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in diagnosis and treatment of thyroid diseases.	Class B
112	Anti-TM (CLIA) Controls	160201248MT	69471455248WD	The Anti-TM controls are intended for performing quality control procedures with MAGLUMI Anti-TM assay when used for the quantitative determination of Anti-TM in human serum and plasma.	Class B
113	Thyroglobulin (CLIA)	130253006M; 130653006M; 130753006M	69471455249WF	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Thyroglobulin (TG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in monitoring of patients with postoperative thyroid ablation.	Class B
114	Thyroglobulin (CLIA) Controls	160201249MT	69471455249WF	The Thyroglobulin controls are intended for performing quality control procedures with MAGLUMI Thyroglobulin assay when used for the quantitative determination of Thyroglobulin in human serum and plasma.	Class B
115	Anti-TPO (CLIA)	130253011M; 130653011M; 130753011M	69471455250VY	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-TPO in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed thyroid diseases.	Class B
116	Anti-TPO (CLIA) Controls	160201250MT	69471455250VY	The Anti-TPO controls are intended for performing quality control procedures with MAGLUMI Anti-TPO assay when used for the quantitative determination of Anti-TPO in human serum and plasma.	Class B
117	Insulin (CLIA)	130255002M; 130655002M; 130755002M	69471455264WB	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Insulin (INS) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and treatment of individuals with suspected	Class C

				or confirmed various carbohydrate metabolism disorders, including diabetes mellitus, and hypoglycemia.	
118	Insulin (CLIA) Controls	160201264MT	69471455264WB	The Insulin controls are intended for performing quality control procedures with MAGLUMI Insulin assay when used for the quantitative determination of Insulin in human serum and plasma.	Class C
119	C-Peptide (CLIA)	130255001M; 130655001M; 130755001M	69471455265WD	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of C-Peptide (C-P) in human serum, plasma and urine using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and treatment of patients with abnormal insulin secretion, including diabetes mellitus.	Class C
120	C-Peptide (CLIA) Controls	160201265MT	69471455265WD	The C-Peptide controls are intended for performing quality control procedures with MAGLUMI C-Peptide assay when used for the quantitative determination of C-Peptide in human serum, plasma and urine.	Class C
121	SHBG (CLIA)	130202515M; 130602515M; 130702515M	69471455427WF	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of SHBG in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed androgen disorders.	Class B
122	SHBG (CLIA) Controls	160201427MT	69471455427WF	The SHBG controls are intended for performing quality control procedures with MAGLUMI SHBG assay when used for the quantitative determination of SHBG in human serum and plasma.	Class B
123	AMH (CLIA)	130252014M; 130652014M; 130752014M	69471455230VS	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-Müllerian hormone (AMH) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in assessment of the ovarian reserve.	Class B
124	AMH (CLIA) Controls	160201230MT	69471455230VS	The AMH controls are intended for performing quality control procedures with MAGLUMI AMH assay when used for the quantitative determination of AMH in human serum and plasma.	Class B
125	Androstenedione (CLIA)	130202516M; 130602516M; 130702516M	69471455423W7	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of androstenedione in	Class B

				human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used in the diagnosis and treatment of individuals with excessive levels of androgen (male sex hormone) production.	
126	Androstenedione (CLIA) Controls	160201423MT	69471455423W7	The Androstenedione controls are intended for performing quality control procedures with MAGLUMI Androstenedione assay when used for the quantitative determination of Androstenedione in human serum and plasma.	Class B
127	Calcitonin (CLIA)	130261002M; 130661002M; 130761002M	69471455291WE	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Calcitonin 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 and treatment of individuals with suspected or confirmed diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism.	Class C
128	Calcitonin (CLIA) Controls	160201291MT	69471455291WE	The Calcitonin controls are intended for performing quality control procedures with MAGLUMI Calcitonin assay when used for the quantitative determination of Calcitonin (CT) in human serum and plasma.	Class C
129	17α-OH Progesterone (CLIA)	130270004M; 130670004M; 130770004M	69471455293WJ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of 17α-OH Progesterone (17α-OH P) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and treatment of various disorders of the adrenal glands or the ovaries.	Class B
130	17α-OH Progesterone (CLIA) Controls	160201293MT	69471455293WJ	The 17α-OH Progesterone controls are intended for performing quality control procedures with MAGLUMI 17α-OH Progesterone assay when used for the quantitative determination of 17α-OH Progesterone in human serum and plasma.	Class B
131	Total β HCG (CLIA)	130252003M; 130652003M; 130752003M	69471455257WE	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Total β HCG in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi	Class B

				series Integrated System, and the assay is used for an aid in early detection individuals with suspected pregnancy and monitoring of individuals with confirmed pregnancy.	
132	Total β HCG (CLIA) Controls	160201257MT	69471455257WE	The Total β HCG controls are intended for performing quality control procedures with MAGLUMI Total β HCG assay when used for the quantitative determination of Total β HCG in human serum and plasma.	Class B
133	FSH (CLIA)	130252001M; 130652001M; 130752001M	69471455251W2	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of follicle stimulating hormone (FSH) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in diagnosis and treatment of individuals with suspected or confirmed pituitary gland and gonadal disorders.	Class B
134	FSH (CLIA) Controls	160201251MT	69471455251W2	The FSH controls are intended for performing quality control procedures with MAGLUMI FSH assay when used for the quantitative determination of FSH in human serum and plasma.	Class B
135	LH (CLIA)	130252002M; 130652002M; 130752002M	69471455252W4	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of luteinizing hormone (LH) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and treatment of individuals with suspected or confirmed gonadal dysfunction.	Class B
136	LH (CLIA) Controls	160201252MT	69471455252W4	The LH controls are intended for performing quality control procedures with MAGLUMI LH assay when used for the quantitative determination of LH in human serum and plasma.	Class B
137	Prolactin (CLIA)	130252006M; 130652006M; 130752006M	69471455253W6	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Prolactin (PRL) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and treatment of individuals with suspected or confirmed disorders of the anterior pituitary gland or of the hypothalamus portion of the brain and prolactinomas.	Class B
138	Prolactin	160201253MT	69471455253W6	The Prolactin controls are intended for	Class

	(CLIA) Controls			performing quality control procedures with MAGLUMI Prolactin assay when used for the quantitative determination of Prolactin in human serum and plasma.	B
139	Progesterone (CLIA)	130252009M; 130652009M; 130752009M	69471455254W8	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Progesterone (PROG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in diagnosis and treatment of individuals with suspected or confirmed disorders of the ovaries or placenta.	Class B
140	Progesterone (CLIA) Controls	160201254MT	69471455254W8	The Progesterone controls are intended for performing quality control procedures with MAGLUMI Progesterone assay when used for the quantitative determination of Progesterone in human serum and plasma.	Class B
141	Estradiol (CLIA)	130252007M; 130652007M; 130752007M	69471455256WC	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Estradiol (E2) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and treatment of individuals with suspected or confirmed various hormonal sexual disorders.	Class B
142	Estradiol (CLIA) Controls	160201256MT	69471455256WC	The Estradiol controls are intended for performing quality control procedures with MAGLUMI Estradiol assay when used for the quantitative determination of Estradiol in human serum and plasma.	Class B
143	Testosterone (CLIA)	130252010M; 130652010M; 130752010M	69471455255WA	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Testosterone (TEST) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and treatment of individuals with suspected or confirmed disorders of sex hormones.	Class B
144	Testosterone (CLIA) Controls	160201255MT	69471455255WA	The Testosterone controls are intended for performing quality control procedures with MAGLUMI Testosterone assay when used for the quantitative determination of Testosterone in human serum and plasma.	Class B
145	Free-Testosterone	130252011M; 130652011M;	69471455258WG	The kit is an in vitro chemiluminescence immunoassay for the quantitative	Class B

	(CLIA)	130752011M		determination of Free-Testosterone (F-T) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of male sex hormones (androgens) disorders, female hirsutism (excessive hair) and virilisation (masculinizatin).	
146	Free-Testosterone (CLIA) Controls	160201258MT	69471455258WG	The Free-Testosterone controls are intended for performing quality control procedures with MAGLUMI Free-Testosterone assay when used for the quantitative determination of Free-Testosterone in human serum and plasma.	Class B
147	DHEA-S (CLIA)	130252012M; 130652012M; 130752012M	69471455259WJ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of DHEA-S in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and treatment of individuals with suspected or confirmed adrenal disease.	Class B
148	DHEA-S (CLIA) Controls	160201259MT	69471455259WJ	The DHEA-S controls are intended for performing quality control procedures with MAGLUMI DHEA-S assay when used for the quantitative determination of DHEA-S in human serum and plasma.	Class B
149	25-OH Vitamin D (CLIA)	130261004M; 130661004M; 130761004M	69471455262W7	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of 25-OH Vitamin D (25-OH VD) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in assessment of individuals with suspected or confirmed vitamin D sufficiency.	Class B
150	25-OH Vitamin D (CLIA) Controls	160201262MT	69471455262W7	The 25-OH Vitamin D controls are intended for performing quality control procedures with MAGLUMI 25-OH Vitamin D assay when used for the quantitative determination of 25-OH Vitamin D in human serum and plasma.	Class B
151	PAPP-A (CLIA)	130264003M; 130664003M; 130764003M	69471455261W5	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of PAPP-A in human serum using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in combination with other parameters to evaluate the risk of	Class C

				trisomy 21 (Down syndrome) during the first trimester of pregnancy.	
152	PAPP-A (CLIA) Controls	160201261MT	69471455261W5	The PAPP-A controls are intended for performing quality control procedures with MAGLUMI PAPP-A assay when used for the quantitative determination of PAPP-A in human serum.	Class C
153	free β-HCG (CLIA)	130214005M; 130614005M; 130714005M	69471455294WL	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of free β-HCG in human serum using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in combination with other parameters to evaluate the risk of trisomy 21 (Down syndrome) during the first trimester of pregnancy.	Class C
154	free β-HCG (CLIA) Controls	160201294MT	69471455294WL	The free β-HCG controls are intended for performing quality control procedures with MAGLUMI free β-HCG assay when used for the quantitative determination of free β-HCG in human serum.	Class C
155	Immunoassay Controls	1601010051; 1601010052; 1601010053; 1601010054; 1601010055; 1601010056; 1601010057; 1601010058	69471455351W7	The Immunoassay Controls are intended for performing quality control procedures with MAGLUMI chemiluminesent immunoassay (CLIA) assays when used for the quantitative determination of Total T3, Total T4, Free T3, Free T4, TSH, FSH, LH, Prolactin, Progesterone, Estradiol, Testosterone, Total β HCG, Insulin and C-Peptide in human serum or plasma.	Class C
156	Tumor Marker Controls	1601010061; 1601010062; 1601010063; 1601010064; 1601010065; 1601010066; 1601010067; 1601010068	69471455352W9	The Tumor Marker Controls are intended for performing quality control procedures with MAGLUMI chemiluminesent immunoassay (CLIA) assays when used for the quantitative determination of AFP, CEA, CA125, CA15-3, CA19-9, Free PSA, Total PSA and Ferritin in human serum or plasma.	Class C
157	HSV-1 IgG (CLIA)	130212012M; 130612012M; 130712012M	69471455159WD	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of HSV-1 IgG in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of HSV-1 infection.	Class C
158	HSV-1 IgG (CLIA) Controls	160201159MT	69471455159WD	The HSV-1 IgG controls are intended for performing quality control procedures with MAGLUMI HSV-1 IgG assay when used for the qualitative determination of HSV-1 IgG in human serum and plasma.	Class C
159	CA 19-9	130201037M;	69471455224VX	The kit is an in vitro chemiluminescence	Class

	(CLIA)	130601037M; 130701037M		immunoassay for the quantitative determination of CA 19-9 in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in management of pancreatic cancer.	C
160	CA 19-9 (CLIA) Controls	160201224MT	69471455224VX	The CA 19-9 controls are intended for performing quality control procedures with MAGLUMI CA 19-9 assay when used for the quantitative determination of CA 19-9 in human serum and plasma.	Class C
161	TSH (CLIA)	130203023M; 130603023M; 130703023M	69471455241VX	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of thyroid-stimulating hormone (TSH) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Intergrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed pituitary-thyroid disorders.	Class B
162	TSH (CLIA) Controls	160201241MT	69471455241VX	The TSH controls are intended for performing quality control procedures with MAGLUMI TSH assay when used for the quantitative determination of TSH in human serum and plasma.	Class B
163	total P1NP (CLIA)	130211005M; 130611005M; 130711005M	69471455153VZ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of total P1NP (P1NP) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in monitoring therapy following the diagnosis of osteoporosis in women and in patients diagnosed with Paget's disease of the bone.	Class B
164	total P1NP (CLIA) Controls	160201153MT	69471455153VZ	The total P1NP controls are intended for performing quality control procedures with MAGLUMI total P1NP assay when used for the quantitative determination of total P1NP in human serum and plasma.	Class B
165	β-CTx (CLIA)	130211006M; 130611006M; 130711006M	69471455154W3	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of β-CTx in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the assessment of bone resorption and the diagnosis of osteoporosis.	Class B
166	β-CTx	160201154MT	69471455154W3	The β-CTx controls are intended for	Class

	(CLIA) Controls			performing quality control procedures with MAGLUMI β-CTx assay when used for the quantitative determination of β-CTx in human serum and plasma.	B
167	PlGF (CLIA)	130212010M; 130612010M; 130712010M	69471455157W9	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of placenta growth factor (PlGF) in human serum using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System. It can be combined with other tests and clinical information to assist in the diagnosis of pre-eclampsia.	Class C
168	PlGF (CLIA) Controls	160201157MT	69471455157W9	The PlGF controls are intended for performing quality control procedures with MAGLUMI PlGF assay when used for the quantitative determination of placenta growth factor (PlGF) in human serum.	Class C
169	sFlt-1 (CLIA)	130212011M; 130612011M; 130712011M	69471455158WB	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of soluble fms-like tyrosine kinase-1 (sFlt-1) in human serum using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System. It can be combined with other tests and clinical information to assist in the diagnosis of pre-eclampsia.	Class C
170	sFlt-1 (CLIA) Controls	160201158MT	69471455158WB	The sFlt-1 controls are intended for performing quality control procedures with MAGLUMI sFlt-1 assay when used for the quantitative determination of Soluble fms-like tyrosine kinase-1 (sFlt-1) in human serum.	Class C
171	HSV-1 IgM (CLIA)	130212013M; 130612013M; 130712013M	69471455160VW	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of HSV-1 IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of HSV-1 infection.	Class C
172	HSV-1 IgM (CLIA) Controls	160201160MT	69471455160VW	The HSV-1 IgM controls are intended for performing quality control procedures with MAGLUMI HSV-1 IgM assay when used for the qualitative determination of HSV-1 IgM in human serum and plasma.	Class C
173	HSV-2 IgM (CLIA)	130212014M; 130612014M; 130712014M	69471455161VY	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of HSV-2 IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi	Class C

				series Integrated System, and the assay is used for an aid in the diagnosis of HSV-2 infection.	
174	HSV-2 IgM (CLIA) Controls	160201161MT	69471455161VY	The HSV-2 IgM controls are intended for performing quality control procedures with MAGLUMI HSV-2 IgM assay when used for the qualitative determination of HSV-2 IgM in human serum and plasma.	Class C
175	TNF-α (CLIA)	130216006M; 130616006M; 130716006M	69471455178WH	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of TNF-α in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed some diseases related to TNF-α, such as inflammation and immune diseases.	Class B
176	TNF-α (CLIA) Controls	160201178MT	69471455178WH	The TNF-α controls are intended for performing quality control procedures with MAGLUMI TNF-α assay when used for the quantitative determination of TNF-α in human serum and plasma.	Class B
177	T-Uptake (CLIA)	130203014M; 130603014M; 130703014M	69471455180W4	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of T-Uptake in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in evaluating thyroid function.	Class B
178	T-Uptake (CLIA) Controls	160201180MT	69471455180W4	The T-Uptake controls are intended for performing quality control procedures with MAGLUMI T-Uptake assay when used for the quantitative determination of T-Uptake in human serum and plasma.	Class B
179	MPO (CLIA)	130206021M; 130606021M; 130706021M	69471455187WJ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Myeloperoxidase (MPO) in human plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed cardiovascular inflammation.	Class C
180	MPO (CLIA) Controls	160201187MT	69471455187WJ	The MPO controls are intended for performing quality control procedures with MAGLUMI MPO assay when used for the quantitative determination of Myeloperoxidase (MPO) in human plasma.	Class C
181	Mycoplasma	130219009M;	69471455189WN	The kit is an in vitro chemiluminescence	Class

	pneumoniae IgG (CLIA)	130619009M; 130719009M		immunoassay for the qualitative determination of Mycoplasma pneumoniae IgG in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of Mycoplasma pneumoniae infection.	C
182	Mycoplasma pneumoniae IgG (CLIA) Controls	160201189MT	69471455189WN	The Mycoplasma pneumoniae IgG controls are intended for performing quality control procedures with MAGLUMI Mycoplasma pneumoniae IgG assay when used for the qualitative determination of Mycoplasma pneumoniae IgG in human serum and plasma.	Class C
183	Mycoplasma pneumoniae IgM (CLIA)	130219011M; 130619011M; 130719011M	69471455190W7	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of Mycoplasma pneumoniae IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of Mycoplasma pneumoniae infection.	Class C
184	Mycoplasma pneumoniae IgM (CLIA) Controls	160201190MT	69471455190W7	The Mycoplasma pneumoniae IgM controls are intended for performing quality control procedures with MAGLUMI Mycoplasma pneumoniae IgM assay when used for the qualitative determination of Mycoplasma pneumoniae IgM in human serum and plasma.	Class C
185	Chlamydia pneumoniae IgG (CLIA)	130219010M; 130619010M; 130719010M	69471455191W9	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of Chlamydia pneumoniae IgG in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of Chlamydia pneumoniae infection.	Class C
186	Chlamydia pneumoniae IgG (CLIA) Controls	160201191MT	69471455191W9	The Chlamydia pneumoniae IgG controls are intended for performing quality control procedures with MAGLUMI Chlamydia pneumoniae IgG assay when used for the qualitative determination of Chlamydia pneumoniae IgG in human serum and plasma.	Class C
187	Chlamydia pneumoniae IgM (CLIA)	130219012M; 130619012M; 130719012M	69471455192WB	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of Chlamydia pneumoniae IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay	Class C

				analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of Chlamydia pneumoniae infection.	
188	Chlamydia pneumoniae IgM (CLIA) Controls	160201192MT	69471455192WB	The Chlamydia pneumoniae IgM controls are intended for performing quality control procedures with MAGLUMI Chlamydia pneumoniae IgM assay when used for the qualitative determination of Chlamydia pneumoniae IgM in human serum and plasma.	Class C
189	Thrombin-Antithrombin III Complex (CLIA)	130218001M; 130618001M; 130718001M	69471455234W2	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Thrombin-Antithrombin III Complex (TAT) in human plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed thrombotic diseases.	Class C
190	Thrombin-Antithrombin III Complex (CLIA) Controls	160201234MT	69471455234W2	The Thrombin-Antithrombin III Complex (TAT) controls are intended for performing quality control procedures with MAGLUMI Thrombin-Antithrombin III Complex assay when used for the quantitative determination of TAT in human plasma.	Class C
191	Thrombomodulin (CLIA)	130218002M; 130618002M; 130718002M	69471455235W4	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Thrombomodulin (TM) in human plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed endothelial cell injury.	Class C
192	Thrombomodulin (CLIA) Controls	160201235MT	69471455235W4	The Thrombomodulin (TM) controls are intended for performing quality control procedures with MAGLUMI Thrombomodulin assay when used for the quantitative determination of TM in human plasma.	Class C
193	α2-Plasmininhibitor-Plasmin Complex (CLIA)	130218003M; 130618003M; 130718003M	69471455236W6	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of α2-Plasmininhibitor-Plasmin Complex (PIC) in human plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed fibrinolytic diseases.	Class C
194	α2-Plasmininhibi	160201236MT	69471455236W6	The α2-Plasmininhibitor-Plasmin Complex (PIC) controls are intended for	Class C

	tor-Plasmin Complex (CLIA) Controls			performing quality control procedures with MAGLUMI α2-Plasmininhibitor-Plasmin Complex assay when used for the quantitative determination of PIC in human plasma.	
195	Tissue plasminogen activator-Plasminogen activator inhibitor Complex (CLIA)	130218004M; 130618004M; 130718004M	69471455237W8	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Tissue plasminogen activator-Plasminogen activator inhibitor Complex (tPAIC) in human plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used to reflect the state of the fibrinolytic system and aid in the diagnosis of individuals with suspected or confirmed cardiovascular diseases.	Class C
196	Tissue plasminogen activator-Plasminogen activator inhibitor Complex (CLIA) Controls	160201237MT	69471455237W8	The Tissue plasminogen activator-Plasminogen activator inhibitor Complex (tPAIC) controls are intended for performing quality control procedures with MAGLUMI Tissue plasminogen activator-Plasminogen activator inhibitor Complex assay when used for the quantitative determination of tPAIC in human plasma.	Class C
197	Unconjugated Estriol (CLIA)	130252008M; 130652008M; 130752008M	69471455260W3	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Unconjugated Estriol (uE3) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the assessment of abnormal pregnancies.	Class C
198	Unconjugated Estriol (CLIA) Controls	160201260MT	69471455260W3	The Unconjugated Estriol controls are intended for performing quality control procedures with MAGLUMI Unconjugated Estriol assay when used for the quantitative determination of Unconjugated Estriol (uE3) in human serum and plasma.	Class C
199	Homocysteine (CLIA)	130206024M; 130606024M; 130706024M	69471455269WM	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Homocysteine in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of hyperhomocysteinemia and the evaluation of cardiovascular disease risk.	Class C
200	Homocysteine (CLIA) Controls	160201269MT	69471455269WM	The Homocysteine controls are intended for performing quality control procedures with MAGLUMI	Class C

				Homocysteine assay when used for the quantitative determination of Homocysteine (HCY) in human serum and plasma.	
201	Anti-Cardiolipin IgG (CLIA)	130217017M; 130617017M; 130717017M	69471455436WG	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-Cardiolipin IgG (aCL IgG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Antiphospholipid syndrome (APS) and Systemic Lupus Erythematodes (SLE).	Class B
202	Anti-Cardiolipin IgG (CLIA) Controls	160201436MT	69471455436WG	The Anti-Cardiolipin IgG controls are intended for performing quality control procedures with MAGLUMI Anti-Cardiolipin IgG assay when used for the quantitative determination of anti-Cardiolipin IgG (aCL IgG) in serum and plasma.	Class B
203	Anti-Cardiolipin IgM (CLIA)	130217016M; 130617016M; 130717016M	69471455437WJ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-Cardiolipin IgM (aCL IgM) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Antiphospholipid syndrome (APS) and Systemic Lupus Erythematodes (SLE).	Class B
204	Anti-Cardiolipin IgM (CLIA) Controls	160201437MT	69471455437WJ	The Anti-Cardiolipin IgM controls are intended for performing quality control procedures with MAGLUMI Anti-Cardiolipin IgM assay when used for the quantitative determination of anti-Cardiolipin IgM (aCL IgM) in serum and plasma.	Class B
205	Anti-β2-Glycoprotein 1 IgG (CLIA)	130217018M; 130617018M; 130717018M	69471455440W7	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-β2-Glycoprotein 1 IgG (β2-GP1 IgG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Antiphospholipid syndrome (APS) and Systemic Lupus Erythematodes (SLE).	Class B
206	Anti-β2-Glycoprotein 1 IgG (CLIA) Controls	160201440MT	69471455440W7	The Anti-β2-Glycoprotein 1 IgG controls are intended for performing quality control procedures with MAGLUMI Anti-β2-Glycoprotein 1 IgG assay when	Class B

				used for the quantitative determination of anti-β2-Glycoprotein 1 IgG (β2-GP1 IgG) in human serum and plasma.	
207	Anti-β2-Glycoprotein 1 IgM (CLIA)	130217019M; 130617019M; 130717019M	69471455441W9	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-β2-Glycoprotein 1 IgM (β2-GP1 IgM) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Antiphospholipid syndrome (APS) and Systemic Lupus Erythematodes (SLE).	Class B
208	Anti-β2-Glycoprotein 1 IgM (CLIA) Controls	160201441MT	69471455441W9	The Anti-β2-Glycoprotein 1 IgM controls are intended for performing quality control procedures with MAGLUMI Anti-β2-Glycoprotein 1 IgM assay when used for the quantitative determination of anti-β2-Glycoprotein 1 IgM (β2-GP1 IgM) in human serum and plasma.	Class B
209	EBV NA IgA (CLIA)	130215008M; 130615008M; 130715008M	69471455451WC	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of EBV NA IgA in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of EBV infection.	Class C
210	EBV NA IgA (CLIA) Controls	160201451MT	69471455451WC	The EBV NA IgA controls are intended for performing quality control procedures with MAGLUMI EBV NA IgA assay when used for the qualitative determination of EBV NA IgA in human serum and plasma.	Class C
211	PAP (CLIA)	130251006M; 130651006M; 130751006M	69471455456WN	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Prostatic Acid Phosphatase (PAP) in human serum using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in monitoring of bone metastases in patients with prostate cancer.	Class C
212	PAP (CLIA) Controls	160201456MT	69471455456WN	The PAP controls are intended for performing quality control procedures with MAGLUMI PAP assay when used for the quantitative determination of PAP in human serum.	Class C
213	Pepsinogen I (CLIA)	130251019M; 130651019M; 130751019M	69471455457WQ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Pepsinogen I (PG I) in human serum and plasma using the MAGLUMI series Fully-auto	Class C

				chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in assessment of the function of gastrine gland cell, and aids in the treatment and monitoring of gastric cancer.	
214	Pepsinogen I (CLIA) Controls	160201457MT	69471455457WQ	The Pepsinogen I controls are intended for performing quality control procedures with MAGLUMI Pepsinogen I assay when used for the quantitative determination of Pepsinogen I (PG I) in human serum and plasma.	Class C
215	Pepsinogen II (CLIA)	130251020M; 130651020M; 130751020M	69471455458WS	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Pepsinogen II (PG II) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the assessment of the lesion of fundic gland, and aid in the treatment and monitoring of gastric cancer.	Class C
216	Pepsinogen II (CLIA) Controls	160201458MT	69471455458WS	The Pepsinogen II controls are intended for performing quality control procedures with MAGLUMI Pepsinogen II assay when used for the quantitative determination of Pepsinogen II (PG II) in human serum and plasma.	Class C
217	Vitamin B12 (CLIA)	130263002M; 130663002M; 130763002M	69471455459WU	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Vitamin B12 (Vit B12) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and treatment of megaloblastic anemias.	Class B
218	Vitamin B12 (CLIA) Controls	160201459MT	69471455459WU	The Vitamin B12 controls are intended for performing quality control procedures with MAGLUMI Vitamin B12 assay when used for the quantitative determination of Vitamin B12 in human serum and plasma.	Class B
219	IGF-I (CLIA)	130255007M; 130655007M; 130755007M	69471455460WD	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Insulin-like-growth factor 1 (IGF-I) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the assessment of individuals with suspected or confirmed growth disorders.	Class B
220	IGF-I (CLIA) Controls	160201460MT	69471455460WD	The IGF-I controls are intended for performing quality control procedures	Class B

				with MAGLUMI IGF-I assay when used for the quantitative determination of IGF-I in human serum and plasma.	
221	D-Dimer (CLIA)	130256008M; 130656008M; 130756008M	69471455461WF	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of D-Dimer in human plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in diagnosis the exclusion of individuals with suspected or confirmed deep venous thromboembolism (DVT) and disseminated intravascular coagulation (DIC), and aid in monitoring the therapy for thrombolysis patients.	Class C
222	D-Dimer (CLIA) Controls	160201461MT	69471455461WF	The D-Dimer controls are intended for performing quality control procedures with MAGLUMI D-Dimer assay when used for the quantitative determination of D-Dimer in human plasma.	Class C
223	Laminin (CLIA)	130259004M; 130659004M; 130759004M	69471455462WH	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Laminin (LN) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed hepatic fibrosis.	Class B
224	Laminin (CLIA) Controls	160201462MT	69471455462WH	The Laminin controls are intended for performing quality control procedures with MAGLUMI Laminin assay when used for the quantitative determination of Laminin (LN) in human serum and plasma.	Class B
225	Col IV (CLIA)	130259003M; 130659003M; 130759003M	69471455463WK	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Type IV collagen (C IV) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed hepatic fibrosis.	Class B
226	Col IV (CLIA) Controls	160201463MT	69471455463WK	The Col IV controls are intended for performing quality control procedures with MAGLUMI Col IV assay when used for the quantitative determination of Type IV collagen (C IV) in human serum and plasma.	Class B
227	Hyaluronic Acid (CLIA)	130259001M; 130659001M; 130759001M	69471455464WM	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Hyaluronic Acid (HA) in human serum and plasma using the	Class B

				MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed hepatic fibrosis.	
228	Hyaluronic Acid (CLIA) Controls	160201464MT	69471455464WM	The Hyaluronic Acid controls are intended for performing quality control procedures with MAGLUMI Hyaluronic Acid assay when used for the quantitative determination of Hyaluronic Acid (HA) in human serum and plasma.	Class B
229	PIIIP N-P (CLIA)	130259002M; 130659002M; 130759002M	69471455465WP	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of type III Procollagen N-terminal peptide (PIIIP N-P) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed hepatic fibrosis.	Class B
230	PIIIP N-P (CLIA) Controls	160201465MT	69471455465WP	The PIIIP N-P controls are intended for performing quality control procedures with MAGLUMI PIIIP N-P assay when used for the quantitative determination of PIIIP N-P in human serum and plasma.	Class B
231	Cholylglycine (CLIA)	130259005M; 130659005M; 130759005M	69471455466WR	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Cholylglycine (CG) in human serum using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and assessment of individuals with suspected or confirmed hepatobiliary diseases.	Class B
232	Cholylglycine (CLIA) Controls	160201466MT	69471455466WR	The Cholylglycine controls are intended for performing quality control procedures with MAGLUMI Cholylglycine assay when used for the quantitative determination of Cholylglycine in human serum.	Class B
233	Growth Hormone (CLIA)	130270001M; 130670001M; 130770001M	69471455467WT	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Growth Hormone (GH) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in assessment of pituitary gland and disorder of growth hormone caused by non-pituitary disease.	Class B
234	Growth Hormone	160201467MT	69471455467WT	The Growth Hormone controls are intended for performing quality control	Class B

	(CLIA) Controls			procedures with MAGLUMI Growth Hormone assay when used for the quantitative determination of Growth Hormone in human serum and plasma.	
235	Cortisol (CLIA)	130270002M; 130670002M; 130770002M	69471455468WV	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Cortisol in human serum, plasma and urine using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and treatment of disorders of individuals with suspected or confirmed the adrenal gland.	Class B
236	Cortisol (CLIA) Controls	160201468MT	69471455468WV	The Cortisol controls are intended for performing quality control procedures with MAGLUMI Cortisol assay when used for the quantitative determination of Cortisol in human serum, plasma and urine.	Class B
237	IAA (CLIA)	130255003M; 130655003M; 130755003M	69471455469WX	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of insulin autoantibodies (IAA) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed diabetes mellitus type 1.	Class C
238	IAA (CLIA) Controls	160201469MT	69471455469WX	The IAA controls are intended for performing quality control procedures with MAGLUMI IAA assay when used for the quantitative determination of IAA in human serum and plasma.	Class C
239	Anti-GAD (CLIA)	130255005M; 130655005M; 130755005M	69471455470WG	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Glutamic acid decarboxylase antibody (Anti-GAD) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed diabetes mellitus type 1.	Class C
240	Anti-GAD (CLIA) Controls	160201470MT	69471455470WG	The Anti-GAD controls are intended for performing quality control procedures with MAGLUMI Anti-GAD assay when used for the quantitative determination of Anti-GAD in human serum and plasma.	Class C
241	PCT (CLIA)	130266001M; 130666001M; 130766001M	69471455471WJ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of PCT in human serum	Class B

				and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed disease of bacterial infections.	
242	PCT (CLIA) Controls	160201471MT	69471455471WJ	The PCT controls are intended for performing quality control procedures with MAGLUMI PCT assay when used for the quantitative determination of PCT in human serum and plasma.	Class B
243	Proinsulin (CLIA)	130255004M; 130655004M; 130755004M	69471455472WL	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of proinsulin (Pro-INS) in human serum using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the assessment of the function of pancreas islets.	Class B
244	Proinsulin (CLIA) Controls	160201472MT	69471455472WL	The Proinsulin controls are intended for performing quality control procedures with MAGLUMI Proinsulin assay when used for the quantitative determination of Proinsulin (Pro-INS) in human serum.	Class B
245	ACTH (CLIA)	130270003M; 130670003M; 130770003M	69471455473WN	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Adrenocorticotropic hormone (ACTH) in human plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and treatment of disorders of individuals with suspected or confirmed adrenal glands.	Class B
246	ACTH (CLIA) Controls	160201473MT	69471455473WN	The ACTH controls are intended for performing quality control procedures with MAGLUMI ACTH assay when used for the quantitative determination of ACTH in human plasma.	Class B
247	Intact PTH (CLIA)	130261001M; 130661001M; 130761001M	69471455474WQ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Parathyroid Hormone (PTH) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in assessment of parathyroid function and in the differential diagnosis of hypercalcemia and hypocalcemia.	Class B
248	Intact PTH (CLIA) Controls	160201474MT	69471455474WQ	The Intact PTH controls are intended for performing quality control procedures with MAGLUMI Intact PTH assay when used for the quantitative determination of PTH in human serum and plasma.	Class B

249	Osteocalcin (CLIA)	130261003M; 130661003M; 130761003M	69471455475WS	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Osteocalcin in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the assessment of osteoporosis and bone synthesis after bone injury.	Class B
250	Osteocalcin (CLIA) Controls	160201475MT	69471455475WS	The Osteocalcin controls are intended for performing quality control procedures with MAGLUMI Osteocalcin assay when used for the quantitative determination of Osteocalcin (also called bone GLA protein, BGP) in human serum and plasma.	Class B
251	HSV-2 IgG (CLIA)	130262008M; 130662008M; 130762008M	69471455479X2	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of HSV-2 IgG in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of HSV-2 infection.	Class C
252	HSV-2 IgG (CLIA) Controls	160201479MT	69471455479X2	The HSV-2 IgG controls are intended for performing quality control procedures with MAGLUMI HSV-2 IgG assay when used for the qualitative determination of HSV-2 IgG in human serum and plasma.	Class C
253	HSV-1/2 IgG (CLIA)	130262007M; 130662007M; 130762007M	69471455480WK	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of HSV-1/2 IgG in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of HSV infection.	Class C
254	HSV-1/2 IgG (CLIA) Controls	160201480MT	69471455480WK	The HSV-1/2 IgG controls are intended for performing quality control procedures with MAGLUMI HSV-1/2 IgG assay when used for the qualitative determination of HSV-1/2 IgG in human serum and plasma.	Class C
255	HSV-1/2 IgM (CLIA)	130262009M; 130662009M; 130762009M	69471455484WT	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of HSV-1/2 IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of HSV infection.	Class C
256	HSV-1/2 IgM (CLIA)	160201484MT	69471455484WT	The HSV-1/2 IgM controls are intended for performing quality control	Class C

	Controls			procedures with MAGLUMI HSV-1/2 IgM assay when used for the qualitative determination of HSV-1/2 IgM in human serum and plasma.	
257	Tacrolimus (CLIA)	130257003M; 130657003M; 130757003M	69471455485WV	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Tacrolimus in human whole blood using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the management of transplant patients receiving tacrolimus therapy.	Class C
258	Tacrolimus (CLIA) Controls	160201485MT	69471455485WV	The Tacrolimus controls are intended for performing quality control procedures with MAGLUMI Tacrolimus assay when used for the quantitative determination of Tacrolimus in human whole blood.	Class C
259	Cyclosporine (CLIA)	130257001M; 130657001M; 130757001M	69471455486WX	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Cyclosporine (CSA) in human whole blood using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the management of transplant patients receiving cyclosporine therapy.	Class C
260	Cyclosporine (CLIA) Controls	160201486MT	69471455486WX	The Cyclosporine controls are intended for performing quality control procedures with MAGLUMI Cyclosporine assay when used for the quantitative determination of Cyclosporine (CSA) in human whole blood.	Class C
261	Digoxin (CLIA)	130257002M; 130657002M; 130757002M	69471455487WZ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Digoxin in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to ensure appropriate therapy.	Class C
262	Digoxin (CLIA) Controls	160201487MT	69471455487WZ	The Digoxin controls are intended for performing quality control procedures with MAGLUMI Digoxin assay when used for the quantitative determination of Digoxin in human serum and plasma.	Class C
263	Albumin (CLIA)	130254002M; 130654002M; 130754002M	69471455488X3	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Albumin (ALB) in human urine using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi	Class B

				series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed kidney diseases.	
264	Albumin (CLIA) Controls	160201488MT	69471455488X3	The Albumin controls are intended for performing quality control procedures with MAGLUMI Albumin assay when used for the quantitative determination of Albumin (ALB) in human urine.	Class B
265	β2-Microglobulin (CLIA)	130254001M; 130654001M; 130754001M	69471455489X5	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of β2-Microglobulin (β2-MG) in human serum, plasma and urine using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of kidney disease and lymphoproliferative diseases such as multiple myelom.	Class C
266	β2-Microglobulin (CLIA) Controls	160201489MT	69471455489X5	The β2-Microglobulin controls are intended for performing quality control procedures with MAGLUMI β2-Microglobulin assay when used for the quantitative determination of β2-Microglobulin in human serum, plasma and urine.	Class C
267	Myoglobin (CLIA)	130256003M; 130656003M; 130756003M	69471455490WN	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Myoglobin in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed myocardial infarction.	Class C
268	Myoglobin (CLIA) Controls	160201490MT	69471455490WN	The Myoglobin controls are intended for performing quality control procedures with MAGLUMI Myoglobin assay when used for the quantitative determination of Myoglobin in human serum and plasma.	Class C
269	CK-MB (CLIA)	130256001M; 130656001M; 130756001M:	69471455491WQ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of CK-MB in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used in the diagnosis and treatment of individuals with suspected or confirmed myocardial infarction and muscle diseases.	Class C
270	CK-MB (CLIA) Controls	160201491MT	69471455491WQ	The CK-MB controls are intended for performing quality control procedures with MAGLUMI CK-MB assay when used for the quantitative determination	Class C

				of CK-MB in human serum and plasma.	
271	NT-proBNP (CLIA)	130256004M; 130656004M; 130756004M	69471455492WS	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of NT-proBNP in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of patients with heart failure.	Class C
272	NT-proBNP (CLIA) Controls	160201492MT	69471455492WS	The NT-proBNP controls are intended for performing quality control procedures with MAGLUMI NT-proBNP assay when used for the quantitative determination of NT-proBNP in human serum and plasma.	Class C
273	hs-cTnI (CLIA)	130256014M; 130656014M; 130756014M	69471455493WU	The kit is an in vitro chemiluminescence immunoassay for the high sensitivity quantitative determination of cardiac troponin I (cTnI) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and treatment of individuals with suspected or confirmed myocardial infarction and cardiac muscle damage.	Class C
274	hs-cTnI (CLIA) Controls	160201493MT	69471455493WU	The hs-cTnI controls are intended for performing quality control procedures with MAGLUMI hs-cTnI assay when used for the quantitative determination of cardiac troponin I (cTnI) in human serum and plasma.	Class C
275	hs-CRP (CLIA)	130206023M; 130606023M; 130706023M	69471455494WW	The kit is an in vitro chemiluminescence immunoassay for the high sensitivity quantitative determination of C-reactive protein (CRP) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in assessment of individuals with suspected or confirmed risk of cardiovascular disease.	Class C
276	hs-CRP (CLIA) Controls	160201494MT	69471455494WW	The hs-CRP controls are intended for performing quality control procedures with MAGLUMI hs-CRP assay when used for the quantitative determination of CRP in human serum and plasma.	Class C
277	IgG (CLIA)	130258005M; 130658005M; 130758005M	69471455497X4	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of IgG in human serum, plasma and urine using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the assessment of the	Class B

				function of immunity and diagnosis of individuals with suspected or confirmed immunological diseases.	
278	IgG (CLIA) Controls	160201497MT	69471455497X4	The IgG controls are intended for performing quality control procedures with MAGLUMI IgG assay when used for the quantitative determination of IgG in human serum, plasma and urine.	Class B
279	IgE (CLIA)	130258001M; 130658001M; 130758001M	69471455498X6	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of total Immunoglobulin E (IgE) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed allergic disorders.	Class B
280	IgE (CLIA) Controls	160201498MT	69471455498X6	The IgE controls are intended for performing quality control procedures with MAGLUMI IgE assay when used for the quantitative determination of IgE in human serum and plasma.	Class B
281	IgA (CLIA)	130258004M; 130658004M; 130758004M	69471455499X8	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of IgA in human serum, plasma and urine using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the assessment of the function of immunity and diagnosis of individuals with suspected or confirmed immunological diseases.	Class B
282	IgA (CLIA) Controls	160201499MT	69471455499X8	The IgA controls are intended for performing quality control procedures with MAGLUMI IgA assay when used for the quantitative determination of IgA in human serum, plasma and urine.	Class B
283	IgM (CLIA)	130258002M; 130658002M; 130758002M	69471455500VY	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the assessment of the function of immunity and diagnosis of individuals with suspected or confirmed immunological diseases.	Class B
284	IgM (CLIA) Controls	160201500MT	69471455500VY	The IgM controls are intended for performing quality control procedures with MAGLUMI IgM assay when used for the quantitative determination of IgM in human serum and plasma.	Class B
285	EBV EA IgG (CLIA)	130265001M; 130665001M;	694714551001HE	The kit is an in vitro chemiluminescence immunoassay for the qualitative	Class C

		130765001M		determination of EBV EA IgG in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of EB viral infection.	
286	EBV EA IgG (CLIA) Controls	1602011001MT	694714551001HE	The EBV EA IgG controls are intended for performing quality control procedures with MAGLUMI EBV EA IgG assay when used for the qualitative determination of EBV EA IgG in human serum and plasma.	Class C
287	EBV NA IgG (CLIA)	130265006M; 130665006M; 130765006M	694714551002HG	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of EBV NA IgG in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of EB viral infection.	Class C
288	EBV NA IgG (CLIA) Controls	1602011002MT	694714551002HG	The EBV NA IgG controls are intended for performing quality control procedures with MAGLUMI EBV NA IgG assay when used for the qualitative determination of EBV NA IgG in human serum and plasma.	Class C
289	EBV VCA IgG (CLIA)	130265003M; 130665003M; 130765003M	694714551003HJ	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of EBV VCA IgG in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of EB viral infection.	Class C
290	EBV VCA IgG (CLIA) Controls	1602011003MT	694714551003HJ	The EBV VCA IgG controls are intended for performing quality control procedures with MAGLUMI EBV VCA IgG assay when used for the qualitative determination of EBV VCA IgG in human serum and plasma.	Class C
291	EBV VCA IgM (CLIA)	130265004M; 130665004M; 130765004M	694714551004HL	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of EBV VCA IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of EB viral infection.	Class C
292	EBV VCA IgM (CLIA) Controls	1602011004MT	694714551004HL	The EBV VCA IgM controls are intended for performing quality control procedures with MAGLUMI EBV VCA IgM assay when used for the qualitative determination of EBV VCA IgM in human serum and plasma.	Class C

293	EBV VCA IgA (CLIA)	130265005M; 130665005M; 130765005M	694714551005HN	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of EBV VCA IgA in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of EB viral infection.	Class C
294	EBV VCA IgA (CLIA) Controls	1602011005MT	694714551005HN	The EBV VCA IgA controls are intended for performing quality control procedures with MAGLUMI EBV VCA IgA assay when used for the qualitative determination of EBV VCA IgA in human serum and plasma.	Class C
295	EBV EA IgA (CLIA)	130265002M; 130665002M; 130765002M	694714551006HQ	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of EBV EA IgA in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of EB viral infection.	Class C
296	EBV EA IgA (CLIA) Controls	1602011006MT	694714551006HQ	The EBV EA IgA controls are intended for performing quality control procedures with MAGLUMI EBV EA IgA assay when used for the qualitative determination of EBV EA IgA in human serum and plasma.	Class C
297	TPA (CLIA)	130201043M; 130601043M; 130701043M	694714551012HK	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Tissue polypeptide antigen (TPA) in human serum using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for the management of patients with tumours arising from epithelial cells, e.g. carcinomas of the lung, breast, gastrointestinal tract, and urinary bladder.	Class C
298	TPA (CLIA) Controls	1602011012MT	694714551012HK	The TPA controls are intended for performing quality control procedures with MAGLUMI TPA assay when used for the quantitative determination of TPA in human serum.	Class C
299	Syphilis (CLIA)	130269003M; 130669003M; 130769003M	694714551013HM	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of total antibodies to Treponema pallidum (T. pallidum) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of Syphilis infection.	Class C

300	Syphilis (CLIA) Controls	1602011013MT	694714551013HM	The Syphilis controls are intended for performing quality control procedures with MAGLUMI Syphilis assay when used for the qualitative determination of total antibodies to Treponema pallidum (T. pallidum) in human serum or plasma.	Class C
301	H.pylori IgA (CLIA)	130251028M; 130651028M; 130751028M	694714551014HP	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of H.pylori IgA in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of H.pylori infection.	Class B
302	H.pylori IgA (CLIA) Controls	1602011014MT	694714551014HP	The H.pylori IgA controls are intended for performing quality control procedures with MAGLUMI H.pylori IgA assay when used for the qualitative determination of H.pylori IgA in human serum and plasma.	Class B
303	H.pylori IgM (CLIA)	130251027M; 130651027M; 130751027M	694714551015HR	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of H.pylori IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of H.pylori infection.	Class B
304	H.pylori IgM (CLIA) Controls	1602011015MT	694714551015HR	The H.pylori IgM controls are intended for performing quality control procedures with MAGLUMI H.pylori IgM assay when used for the qualitative determination of H.pylori IgM in human serum and plasma.	Class B
305	CRP (CLIA)	130266002M; 130666002M; 130766002M	694714551019HZ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of C-reactive protein (CRP) 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 a nonspecific marker of inflammation.	Class B
306	CRP (CLIA) Controls	1602011019MT	694714551019HZ	The CRP controls are intended for performing quality control procedures with MAGLUMI CRP assay when used for the quantitative determination of CRP in human serum and plasma.	Class B
307	Preaccu for Prenatal Screening	22010315	69471455Preaccu6W	Trisomy 21 and Trisomy 18/13 screening during the first trimester.	Class C
308	Anti-Ro-52 IgG (CLIA)	130217026M; 130617026M; 130717026M	694714551022HN	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-Ro-52 IgG in human serum and plasma using the MAGLUMI series Fully-auto	Class B

				chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed autoimmune diseases such as sjögren's syndrom.	
309	Anti-Ro-52 IgG (CLIA) Controls	1602011022MT	694714551022IIN	The Anti-Ro-52 IgG controls are intended for performing quality control procedures with MAGLUMI Anti-Ro-52 IgG assay when used for the quantitative determination of Anti-Ro-52 IgG in human serum and plasma.	Class B
310	Anti-Nucleosomes IgG (CLIA)	130217024M; 130617024M; 130717024M	694714551020HJ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-Nucleosomes IgG in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed systemic lupus erythematosus (SLE) or lupus nephritis and the assessment of disease activity in individuals with confirmed systemic lupus erythematosus (SLE).	Class B
311	Anti-Nucleosomes IgG (CLIA) Controls	1602011020MT	694714551020IIJ	The Anti-Nucleosomes IgG controls are intended for performing quality control procedures with MAGLUMI Anti-Nucleosomes IgG assay when used for the quantitative determination of Anti-Nucleosomes IgG in human serum and plasma.	Class B
312	Anti-PM-Scl IgG (CLIA)	130217025M; 130617025M; 130717025M	694714551021HL	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-PM-Scl IgG in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed polymyositis/scleroderma overlap syndrome.	Class B
313	Anti-PM-Scl IgG (CLIA) Controls	1602011021MT	694714551021HL	The Anti-PM-Scl IgG controls are intended for performing quality control procedures with MAGLUMI Anti-PM-Scl IgG assay when used for the quantitative determination of Anti-PM-Scl IgG in human serum and plasma.	Class B
314	CMV IgM (CLIA)	130262006M; 130662006M; 130762006M	69471455482WP	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of CMV IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is	Class C

				used for an aid in the diagnosis of acute or recent CMV infection and used for pre-natal screening of women.	
315	CMV IgM (CLIA) Controls	160201482MT	69471455482WP	The CMV IgM controls are intended for performing quality control procedures with MAGLUMI CMV IgM assay when used for the qualitative determination of CMV IgM in human serum and plasma.	Class C
316	Toxo IgM (CLIA)	130262002M; 130662002M; 130762002M	69471455481WM	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of Toxo IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of acute or recent Toxoplasma gondii infection and used for pre-natal screening of women.	Class C
317	Toxo IgM (CLIA) Controls	160201481MT	69471455481WM	The Toxo IgM controls are intended for performing quality control procedures with MAGLUMI Toxo IgM assay when used for the qualitative determination of Toxo IgM in human serum and plasma.	Class C
318	Rubella IgM (CLIA)	130262004M; 130662004M; 130762004M	69471455483WR	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of Rubella IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of acute or recent rubella infection and used for pre-natal screening of women.	Class C
319	Rubella IgM (CLIA) Controls	160201483MT	69471455483WR	The Rubella IgM controls are intended for performing quality control procedures with MAGLUMI Rubella IgM assay when used for the qualitative determination of Rubella IgM in human serum and plasma.	Class C
320	CMV IgG (CLIA)	130212005M; 130612005M; 130712005M	69471455071VW	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of CMV IgG in human serum using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of CMV infection ,assess the serological status of an individual and used for pre-natal screening of women.	Class C
321	CMV IgG (CLIA) Controls	160201071MT	69471455071VW	The CMV IgG controls are intended for performing quality control procedures with MAGLUMI CMV IgG assay when used for the qualitative determination of CMV IgG in human serum.	Class C
322	Toxo IgG (CLIA)	130212001M; 130612001M;	69471455077WA	The kit is an in vitro chemiluminescence immunoassay for the qualitative	Class C

		130712001M		determination of Toxo IgG in human serum using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of Toxoplasma gondii infection, assess the serological status of an individual and used for pre-natal screening of women.	
323	Toxo IgG (CLIA) Controls	160201077MT	69471455077WA	The Toxo IgG controls are intended for performing quality control procedures with MAGLUMI Toxo IgG assay when used for the qualitative determination of Toxo IgG in human serum.	Class C
324	Rubella IgG (CLIA)	130212003M; 130612003M; 130712003M	69471455076W8	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of Rubella IgG in human serum using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of rubella infection, assess the serological status of an individual and used for pre-natal screening of women.	Class C
325	Rubella IgG (CLIA) Controls	160201076MT	69471455076W8	The Rubella IgG controls are intended for performing quality control procedures with MAGLUMI® Rubella IgG (CLIA) when used for the qualitative determination of Rubella IgG in human serum.	Class C
326	Anti-β2-Glycoprotein 1 IgA (CLIA)	130217027M; 130617027M; 130717027M	69471455439WN	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-β2-Glycoprotein 1 IgA (β2-GP1 IgA) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed antiphospholipid syndrome (APS) and systemic lupus erythematodes (SLE).	Class B
327	Anti-β2-Glycoprotein 1 IgA (CLIA) Controls	160201439MT	69471455439WN	The Anti-β2-Glycoprotein 1 IgA controls are intended for performing quality control procedures with MAGLUMI Anti-β2-Glycoprotein 1 IgA assay when used for the quantitative determination of anti-β2-Glycoprotein 1 IgA (β2-GP1 IgA) in human serum and plasma.	Class B
328	Anti-β2-Glycoprotein 1 (CLIA)	130217030M; 130617030M; 130717030M	69471455442WB	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-β2-Glycoprotein 1 (β2-GP1) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid	Class B

				in the diagnosis of individuals with suspected or confirmed Antiphospholipid syndrome (APS) and Systemic Lupus Erythematodes (SLE).	
329	Anti-β2-Glycoprotein 1 (CLIA) Controls	160201442MT	69471455442WB	The Anti-β2-Glycoprotein 1 controls are intended for performing quality control procedures with MAGLUMI Anti-β2-Glycoprotein 1 assay when used for the quantitative determination of anti-β2-Glycoprotein 1 (β2-GP1) in human serum and plasma.	Class B
330	Anti-Cardiolipin IgA (CLIA)	130217028M; 130617028M; 130717028M	69471455435WE	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of anti-Cardiolipin IgA (aCL IgA) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Antiphospholipid syndrome (APS) and Systemic Lupus Erythematodes (SLE).	Class B
331	Anti-Cardiolipin IgA (CLIA) Controls	160201435MT	69471455435WE	The Anti-Cardiolipin IgA controls are intended for performing quality control procedures with MAGLUMI Anti-Cardiolipin IgA assay when used for the quantitative determination of anti-Cardiolipin IgA (aCL IgA) in human serum and plasma.	Class B
332	Anti-Cardiolipin (CLIA)	130217029M; 130617029M; 130717029M	69471455438WL	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of anti-Cardiolipin (aCL) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Antiphospholipid syndrome (APS) and Systemic Lupus Erythematodes (SLE).	Class B
333	Anti-Cardiolipin (CLIA) Controls	160201438MT	69471455438WL	The Anti-Cardiolipin controls are intended for performing quality control procedures with MAGLUMI Anti-Cardiolipin assay when used for the quantitative determination of anti-Cardiolipin (aCL) in human serum and plasma.	Class B
334	Fibrin/fibrinogen degradation products (CLIA)	130218005M; 130618005M; 130718005M	694714551023IIQ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Fibrin/fibrinogen degradation products (FDP) in human plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of	Class B

				individuals with suspected or confirmed primary and secondary hyperfibrinolysis related diseases.	
335	Fibrin/fibrinogen degradation products (CLIA) Controls	1602011023MT	694714551023HQ	The Fibrin/fibrinogen degradation products controls are intended for performing quality control procedures with MAGLUMI Fibrin/fibrinogen degradation products assay when used for the quantitative determination of Fibrin/fibrinogen degradation products (FDP) in human plasma.	Class B
336	PTH (CLIA)	130211008M; 130611008M; 130711008M	694714551031HP	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of biointact parathyroid hormone PTH(1-84) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed parathyroid disease.	Class B
337	PTH (CLIA) Controls	1602011031MT	694714551031HP	The PTH(1-84) controls are intended for performing quality control procedures with MAGLUMI PTH(1-84) assay when used for the quantitative determination of PTH(1-84) in human serum and plasma.	Class B
338	Anti-PR3 IgG (CLIA)	130217031M; 130617031M; 130717031M	69471455185WE	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-PR3 IgG (PR3 IgG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed granulomatosis with polyangiitis (GPA, formerly: Wegener's granulomatosis(WG)) and other anti-neutrophil cytoplasmic antibody (ANCA) associated vasculitis and assessment of disease activity in individuals with confirmed GPA and other ANCA associated vasculitis.	Class B
339	Anti-PR3 IgG (CLIA) Controls	160201185MT	69471455185WE	The Anti-PR3 IgG controls are intended for performing quality control procedures with MAGLUMI Anti-PR3 IgG assay when used for the quantitative determination of Anti-PR3 IgG (PR3 IgG) in human serum and plasma.	Class B
340	Anti-GBM IgG (CLIA)	130217032M; 130617032M; 130717032M	69471455268WK	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-GBM IgG (GBM IgG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated	Class B

				System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Goodpasture's syndrome, rapid progressive glomerulonephritis, and immune complex glomerulonephritis and other glomerulonephritis.	
341	Anti-GBM IgG (CLIA) Controls	160201268MT	69471455268WK	The Anti-GBM IgG controls are intended for performing quality control procedures with MAGLUMI Anti-GBM IgG assay when used for the quantitative determination of Anti-GBM IgG (GBM IgG) in human serum and plasma.	Class B
342	Toxo IgG (CLIA)	130262001M; 130662001M; 130762001M	69471455476WU	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Toxo IgG in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed Toxoplasma gondii infection, assess the serological status of an individual and used for pre-natal screening of women.	Class C
343	Toxo IgG (CLIA) Controls	160201476MT	69471455476WU	The Toxo IgG controls are intended for performing quality control procedures with MAGLUMI Toxo IgG assay when used for the quantitative determination of Toxo IgG in human serum and plasma.	Class C
344	CMV IgG (CLIA)	130262005M; 130662005M; 130762005M	69471455477WW	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of CMV IgG in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed CMV infection, assess the serological status of an individual and used for pre-natal screening of women.	Class C
345	CMV IgG (CLIA) Controls	160201477MT	69471455477WW	The CMV IgG controls are intended for performing quality control procedures with MAGLUMI CMV IgG assay when used for the quantitative determination of CMV IgG in human serum and plasma.	Class C
346	Rubella IgG (CLIA)	130262003M; 130662003M; 130762003M	69471455478WY	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Rubella IgG in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the management of patients with rubella, assess the	Class C

				serological status of an individual and used for pre-natal screening of women.	
347	Rubella IgG (CLIA) Controls	160201478MT	69471455478WY	The Rubella IgG controls are intended for performing quality control procedures with MAGLUMI Rubella IgG assay when used for the quantitative determination of Rubella IgG in human serum and plasma.	Class C
348	Tacrolimus (CLIA)	1302573003M; 1306573003M; 1307573003M	694714551036HZ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Tacrolimus in human whole blood using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the management of transplant patients receiving tacrolimus therapy.	Class C
349	Tacrolimus (CLIA) Controls	1602011036MT	694714551036HZ	The Tacrolimus controls are intended for performing quality control procedures with MAGLUMI Tacrolimus assay when used for the quantitative determination of Tacrolimus in human whole blood.	Class C
350	Total T3 (CLIA)	1302533003M; 1306533003M; 1307533003M	69471455103917	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of total triiodothyronine (Total T3) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in diagnosis and treatment of individuals with suspected or confirmed thyroid diseases such as hyperthyroidism.	Class B
351	Total T3 (CLIA) Controls	1602011039MT	69471455103917	The Total T3 controls are intended for performing quality control procedures with MAGLUMI Total T3 assay when used for the quantitative determination of Total T3 in human serum and plasma.	Class B
352	Free T3 (CLIA)	1302533005M; 1306533005M; 1307533005M	694714551041HS	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of free triiodothyronine (Free T3) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in diagnosis and treatment of individuals with suspected or confirmed thyroid diseases such as hyperthyroidism.	Class B
353	Free T3 (CLIA) Controls	1602011041MT	694714551041HS	The Free T3 controls are intended for performing quality control procedures with MAGLUMI Free T3 assay when used for the quantitative determination of Free T3 in human serum and plasma.	Class B
354	Total T4 (CLIA)	1302533002M; 1306533002M; 1307533002M	694714551040HQ	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of total thyroxine (Total	Class B

				T4) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in diagnosis and treatment of individuals with suspected or confirmed thyroid diseases.	
355	Total T4 (CLIA) Controls	1602011040MT	694714551040HQ	The Total T4 controls are intended for performing quality control procedures with MAGLUMI Total T4 assay when used for the quantitative determination of Total T4 in human serum and plasma.	Class B
356	Free T4 (CLIA)	1302533004M; 1306533004M; 1307533004M	694714551042HU	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of free thyroxine (Free T4) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in diagnosis and treatment of individuals with suspected or confirmed thyroid diseases.	Class B
357	Free T4 (CLIA) Controls	1602011042MT	694714551042HU	The Free T4 controls are intended for performing quality control procedures with MAGLUMI Free T4 assay when used for the quantitative determination of Free T4 in human serum and plasma.	Class B
358	Testosterone (CLIA)	1302523001M; 1306523001M; 1307523001M	69471455104 7J6	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Testosterone (TEST) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of patients with diseases related to abnormal testosterone levels.	Class B
359	Testosterone (CLIA) Controls	1602011047MT	69471455104 7J6	The Testosterone controls are intended for performing quality control procedures with MAGLUMI Testosterone assay when used for the quantitative determination of Testosterone in human serum and plasma.	Class B
360	Progesterone (CLIA)	1302523003M; 1306523003M; 1307523003M	694714551049JA	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Progesterone (PROG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of patients with diseases related to abnormal progesterone levels such as threatened abortion and luteal insufficiency.	Class B

361	Progesterone (CLIA) Controls	1602011049MT	694714551049JA	The Progesterone controls are intended for performing quality control procedures with MAGLUMI Progesterone assay when used for the quantitative determination of Progesterone in human serum and plasma.	Class B
362	Androstenedione (CLIA)	1302523004M; 1306523004M; 1307523004M	694714551052HX	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Androstenedione in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of patients with polycystic ovary syndrome, adrenal cortical hyperplasia and other diseases.	Class B
363	Androstenedione (CLIA) Controls	1602011052MT	694714551052HX	The Androstenedione controls are intended for performing quality control procedures with MAGLUMI Androstenedione assay when used for the quantitative determination of Androstenedione in human serum and plasma.	Class B
364	Folate (CLIA)	1302633001M; 1306633001M; 1307633001M	694714551043HW	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Folate (FA) in human serum, plasma and red blood cells using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed anemias.	Class B
365	Folate (CLIA) Controls	1602011043MT	694714551043HW	The Folate controls are intended for performing quality control procedures with MAGLUMI Folate assay when used for the quantitative determination of Folate (FA) in human serum, plasma and red blood cells.	Class B
366	Vitamin B12 (CLIA)	1302633002M; 1306633002M; 1307633002M	694714551044HY	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Vitamin B12 (Vit B12) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of patients with diseases related to Vitamin B12 deficiency.	Class B
367	Vitamin B12 (CLIA) Controls	1602011044MT	694714551044HY	The Vitamin B12 controls are intended for performing quality control procedures with MAGLUMI Vitamin B12 assay when used for the quantitative determination of Vitamin B12 in human serum and plasma.	Class B
368	Cyclosporine	1302573001M;	6947145510461J4	The kit is an in vitro chemiluminescence	Class

	(CLIA)	1306573001M; 1307573001M		immunoassay for the quantitative determination of Cyclosporine (CSA) in human whole blood using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the management of transplant patients receiving CSA therapy.	C
369	Cyclosporine (CLIA) Controls	1602011046MT	6947145510464J4	The Cyclosporine controls are intended for performing quality control procedures with MAGLUMI Cyclosporine assay when used for the quantitative determination of Cyclosporine (CSA) in human whole blood.	Class C
370	Rev T3 (CLIA)	1302533006M; 1306533006M; 1307533006M	694714551050HT	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Rev T3 (rT3) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the evaluation of thyroid function.	Class B
371	Rev T3 (CLIA) Controls	1602011050MT	694714551050HT	The Rev T3 (rT3) controls are intended for performing quality control procedures with MAGLUMI Rev T3 assay when used for the quantitative determination of Rev T3 in human serum and plasma.	Class B
372	Influenza A Virus IgM (CLIA)	130219023M 130619023M 130719023M	69471455273WC	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of Influenza A Virus (IAV) IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis and differential diagnosis of individuals with suspected or confirmed Influenza A Virus infection.	Class B
373	Influenza A Virus IgM (CLIA) Controls	160201273MT	69471455273WC	The Influenza A Virus (IAV) IgM controls are intended for performing quality control procedures with MAGLUMI Influenza A Virus IgM assay when used for the qualitative determination of Influenza A Virus IgM in human serum and plasma.	Class B
374	Influenza B Virus IgM (CLIA)	130219024M 130619024M 130719024M	69471455274WE	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of Influenza B Virus (IBV) IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid	Class B

				in the diagnosis and differential diagnosis of individuals with suspected or confirmed Influenza B Virus infection.	
375	Influenza B Virus IgM (CLIA) Controls	160201274MT	69471455274WE	The Influenza B Virus (IBV) IgM controls are intended for performing quality control procedures with MAGLUMI Influenza B Virus IgM assay when used for the qualitative determination of Influenza B Virus IgM in human serum and plasma.	Class B
376	Human Parainfluenza Virus IgM (CLIA)	130219025M 130619025M 130719025M	69471455275WG	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of Human Parainfluenza Virus(HPIV) IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed HPIV infection.	Class B
377	Human Parainfluenza Virus IgM (CLIA) Controls	160201275MT	69471455275WG	The Human Parainfluenza Virus (HPIV) IgM controls are intended for performing quality control procedures with MAGLUMI Human Parainfluenza Virus IgM assay when used for the qualitative determination of Human Parainfluenza Virus IgM in human serum and plasma.	Class B
378	Legionella pneumophila IgM (CLIA)	130219022M 130619022M 130719022M	69471455276WJ	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of Legionella pneumophila (LP) IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed LP infection	Class B
379	Legionella pneumophila IgM (CLIA) Controls	160201276MT	69471455276WJ	The Legionella pneumophila (LP) IgM controls are intended for performing quality control procedures with MAGLUMI Legionella pneumophila IgM assay when used for the qualitative determination of Legionella pneumophila IgM in human serum and plasma.	Class B
380	Respiratory Syncytial Virus IgM (CLIA)	130219019M 130619019M 130719019M	69471455277WL	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of Respiratory Syncytial Virus(RSV) IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed	Class B

				RSV infections.	
381	Respiratory Syncytial Virus IgM (CLIA) Controls	160201277MT	69471455277WL	The Respiratory Syncytial Virus (RSV) IgM controls are intended for performing quality control procedures with MAGLUMI Respiratory Syncytial Virus IgM assay when used for the qualitative determination of Respiratory Syncytial Virus IgM in human serum and plasma.	Class B
382	Adenovirus IgM (CLIA)	130219020M 130619020M 130719020M	69471455278WN	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of Adenovirus (ADV) IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of Adenovirus infection in suspected or confirmed patients.	Class B
383	Adenovirus IgM (CLIA) Controls	160201278MT	69471455278WN	The Adenovirus (ADV) IgM controls are intended for performing quality control procedures with MAGLUMI Adenovirus IgM assay when used for the qualitative determination of Adenovirus IgM in human serum and plasma.	Class B
384	Coxsackievirus B IgM (CLIA)	130219021M 130619021M 130719021M	69471455279WQ	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of Coxsackievirus B (COXB) IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed COXB infection.	Class B
385	Coxsackievirus B IgM (CLIA) Controls	160201279MT	69471455279WQ	The Coxsackievirus B (COXB) IgM controls are intended for performing quality control procedures with MAGLUMI Coxsackievirus B IgM assay when used for the qualitative determination of Coxsackievirus B IgM in human serum and plasma.	Class B
386	Anti-HAV (CLIA)	130260007M 130660007M 130760007M	69471455104SJ2	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of Anti-HAV in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed hepatitis A.	Class B
387	Anti-HAV (CLIA) Controls	1602011045MT	694714551045J2	The Anti-HAV controls are intended for performing quality control procedures with MAGLUMI Anti-HAV assay when used for the qualitative determination of Anti-HAV in human serum and plasma.	Class B
388	HAV IgM	130210025M	69471455450WA	The kit is an in vitro chemiluminescence	Class

	(CLIA)	130610025M 130710025M		immunoassay for the qualitative determination of HAV IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the clinical diagnosis of hepatitis A.	B
389	HAV IgM (CLIA) Controls	160201450MT	69471455450WA	The HAV IgM controls are intended for performing quality control procedures with MAGLUMI HAV IgM assay when used for the qualitative determination of HAV IgM in human serum and plasma.	Class B
390	HEV IgG (CLIA)	130210028M 130610028M 130710028M	69471455214VU	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of HEV IgG in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed HEV infection.	Class B
391	HEV IgG (CLIA) Controls	160201214MT	69471455214VU	The HEV IgG controls are intended for performing quality control procedures with MAGLUMI HEV IgG assay when used for the qualitative determination of HEV IgG in human serum and plasma.	Class B
392	HEV IgM (CLIA)	130210029M 130610029M 130710029M	69471455215VW	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of HEV IgM in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed HEV infection.	Class C
393	HEV IgM (CLIA) Controls	160201215MT	69471455215VW	The HEV IgM controls are intended for performing quality control procedures with MAGLUMI HEV IgM assay when used for the qualitative determination of HEV IgM in human serum and plasma.	Class C
394	Anti-Dengue Virus IgM(CLIA)	130219031M 130619031M 130719031M	69471455403VZ	The kit is an in vitro chemiluminescence immunoassay for the qualitative determination of Anti-Dengue Virus IgM (DENV IgM) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed dengue virus infections.	Class B
395	Anti-Dengue Virus IgM (CLIA) Controls	160201403MT	69471455403VZ	The Anti-Dengue Virus IgM controls are intended for performing quality control procedures with MAGLUMI Anti-Dengue Virus IgM assay when used for	Class B

				the qualitative determination of Anti-Dengue Virus IgM(DENV IgM) in human serum and plasma.	
396	Anti-Dengue Virus IgG(CLIA)	130219030M 130619030M 130719030M	69471455402VX	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-Dengue Virus IgG (DENV IgG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed dengue virus infections.	Class B
397	Anti-Dengue Virus IgG (CLIA) Controls	160201402MT	69471455402VX	The Anti-Dengue Virus IgG controls are intended for performing quality control procedures with MAGLUMI Anti-Dengue Virus IgG assay when used for the quantitative determination of Anti-Dengue Virus IgG(DENV IgG) in human serum and plasma.	Class B
398	Dengue virus NS1 Antigen(CLIA)	130219029M 130619029M 130719029M	69471455401VV	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Dengue virus NS1 Antigen (DENV NS1) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed dengue virus infections	Class C
399	Dengue virus NS1 Antigen (CLIA) Controls	160201401MT	69471455401VV	The Dengue virus NS1 Antigen controls are intended for performing quality control procedures with MAGLUMI Dengue virus NS1 Antigen assay when used for the quantitative determination of Dengue virus NS1 Antigen (DENV NS1) in human serum and plasma.	Class C
400	Anti-DGP IgG (CLIA)	130217023M 130617023M 130717023M	69471455446WK	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-DGP IgG (DGP IgG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed celiac disease.	Class B
401	Anti-DGP IgG (CLIA) Controls	160201446MT	69471455446WK	The Anti-DGP IgG controls are intended for performing quality control procedures with MAGLUMI Anti-DGP IgG assay when used for the quantitative determination of anti-DGP IgG (DGP IgG) in human serum and plasma.	Class B
402	Anti-DGP IgA (CLIA)	130217022M 130617022M 130717022M	69471455445WH	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-DGP IgA (DGP	Class B

				IgA) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed celiac disease.	
403	Anti-DGP IgA (CLIA) Controls	160201445MT	69471455445WH	The Anti-DGP IgA controls are intended for performing quality control procedures with MAGLUMI Anti-DGP IgA assay when used for the quantitative determination of anti-DGP IgA (DGP IgA) in human serum and plasma.	Class B
404	Anti-tissue Transglutaminase IgG (CLIA)	130217021M 130617021M 130717021M	69471455444WF	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-tissue Transglutaminase IgG (tTG IgG) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of individuals with suspected or confirmed celiac disease.	Class B
405	Anti-tissue Transglutaminase IgG (CLIA) Controls	160201444MT	69471455444WF	The Anti-tissue Transglutaminase IgG controls are intended for performing quality control procedures with MAGLUMI Anti-tissue Transglutaminase IgG assay when used for the quantitative determination of anti-tissue Transglutaminase IgG (tTG IgG) in human serum and plasma.	Class B
406	Anti-tissue Transglutaminase IgA (CLIA)	130217020M 130617020M 130717020M	69471455443WD	The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Anti-tissue Transglutaminase IgA (tTG IgA) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of celiac disease in suspected or confirmed patients.	Class B
407	Anti-tissue Transglutaminase IgA (CLIA) Controls	160201443MT	69471455443WD	The Anti-tissue Transglutaminase IgA controls are intended for performing quality control procedures with MAGLUMI Anti-tissue Transglutaminase IgA assay when used for the quantitative determination of anti-tissue Transglutaminase IgA (tTG IgA) in human serum and plasma.	Class B

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Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 105113 0005 Rev. 01

Manufacturer:

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.23, Jinxiu East Road, Pingshan District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer: CN-MF-000005655

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12 105113 0005 Rev. 01

Report No.: GZ2113002

Preceding Certificate No.: V12 105113 0005 Rev. 00

Valid from: 2022-09-01

Valid until: 2025-12-14

Date of Initial Issuance: 2020-12-15

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-09-01

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No. V12 105113 0005 Rev. 01

Classification:	B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

Classification:	B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0607 - Devices intended to be used for detection of pregnancy or fertility testing

Classification:	B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

Classification:	B
Device Group:	W0105 - INFECTIOUS DISEASES
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

Classification:	C
Device Group:	W0101 - CLINICAL CHEMISTRY
IVP Code:	IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

Classification:	C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0301 - Devices intended to be used in screening, diagnosis, staging or monitoring of cancer

Classification:	C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0401 - Devices intended to be used in screening/confirmation of congenital/inherited disorders

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No. V12 105113 0005 Rev. 01

Classification:	C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

Classification:	C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0606 - Devices intended to be used for non-infectious disease staging

Classification:	C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

Classification:	C
Device Group:	W0105 - INFECTIOUS DISEASES
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

Classification:	C
Device Group:	W0201020182 - AUTOMATED IMMUNOCHEMISTRY ANALYSERS - SOFTWARE ACCESSORIES
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0401 - Devices intended to be used in screening/confirmation of congenital/inherited disorders

The validity of this certificate depends on conditions and/or is limited to the following:	- none -

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No. V12 105113 0005 Rev. 01

Revision History:	Rev.	Dated	Report
	00	2020-12-15	GZ2013005

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