

CA-GJLA202401260006

mindray

“Echipamed-Plus” SRL
str. Valea Trandafirilor, 24B, of. 2-7
MD-2001, Chisinau, Moldova
+373 22 234-349

Date: 26.01.2024

LETTER OF AUTHORIZATION

To whom it may concern,

We, Shenzhen Mindray Bio-Medical Electronics Co., Ltd., (“Mindray”) manufacturer of biochemical, immunological and coagulation analyzers, reagents and consumables (“Product(s)”), hereby certify that “Echipamed-Plus” SRL, with business office at str. Valea Trandafirilor, 24B, of. 2-7, MD-2001, Chisinau, Republic of Moldova (“You”) is our official distributor and local representative for registration, sales and service of the Product(s) in Republic of Moldova (“Territory”).

As the manufacturer, Mindray guarantees the Product(s) against defects in materials and workmanship, and provide services based on the standard terms and conditions of Mindray’s warranty policy.

This authorization of distribution rights is valid from the date of issuance to **December 31, 2024**. Mindray reserves the right to terminate the authorization upon fifteen (15) days written notice without any compensation to You.

Neither this Letter of Authorization nor any further extension, will impose any obligation or grant any rights regarding further distribution of the Product(s), nor allow any party to seek compensation for goodwill developed during the term of Letter of Authorization or any further extension.

Best regards,



Duan Liang
General Manager of Sales and Marketing Division, Central Asia Region
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

**SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.**
Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan,
Shenzhen 518057, P.R. China
Tel: +86 755 26582888
Fax: +86 755 26582680
Website: www.mindray.com





Product Service

Certificate

No. Q5 044751 0164 Rev. 05

Holder of Certificate: **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**

Mindray Building
 Keji 12th Road South
 High-Tech Industrial Park
 Nanshan
 518057 Shenzhen
 PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of: Active Medical Devices(intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro Diagnostic Instruments; Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits(intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5_044751_0164_Rev_05

Report No.: SH2305501

Valid from: 2023-09-01
Valid until: 2026-08-31

Date, 2023-06-19

C. Dicks

Christoph Dicks
 Head of Certification/Notified Body





Product Service

Certificate

No. Q5 044751 0164 Rev. 05

Applied Standard(s): EN ISO 13485:2016
 Medical devices - Quality management systems -
 Requirements for regulatory purposes
 (ISO 13485:2016)
 DIN EN ISO 13485:2016

Facility(ies): **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**
 Mindray Building, Keji 12th Road South, High-Tech Industrial Park,
 Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of: Active Medical Devices(intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro Diagnostic Instruments; Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits(intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
 1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen,
 PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of: Active Medical Devices(intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro Diagnostic Instruments; Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits(intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)



ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFICADO ◆ CERTIFICAT



Product Service

Certificate

No. Q5 044751 0164 Rev. 05

For the product(s)/product category (ies):

Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor , Defibrillator/Monitor and Accessories, Electrocardiograph, Anesthesia Machine and accessories, Ventilator, Air compressor, Endoscope Camera System, Endoscope Light Source and accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for invitro diagnostic use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker&Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer , Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer.





DECLARATION OF CONFORMITY

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, located at Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA, hereby confirm that:

We herewith declare that the products listed in Attachment I, Attachment II, Attachment III meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices.

Product Category I : Auto Hematology Analyzer, Semi-auto Chemistry Analyzer, Chemistry Analyzer, Chemiluminescence Immunoassay Analyzer, Sample Processing System, Reagents, Calibrators, and Controls for Auto Hematology Analyzer, Consumables for Chemistry Analyzer, Reagents, Calibrators, and Controls for Chemistry Analyzer, Consumables for Chemiluminescence Immunoassay Analyzer, Reagents, Calibrators, and Controls for Chemiluminescence Immunoassay Analyzer

Products: Attachment I

Classification: The device not in IVDD annex II and not for self-testing/performance evaluation

Conformity Assessment Route: IVDD Annex III (not includes Section 6)

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Product Category II: Reagents, Calibrators, and Controls for Chemiluminescence

Immunoassay Analyzer

Products: Attachment II

Classification: List B in IVDD annex II

Conformity Assessment Route: Annex IV.3

Product Category III: Reagents, Calibrators, and Controls for Chemiluminescence

Immunoassay Analyzer

Products: Attachment III

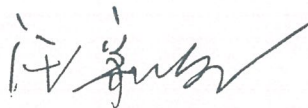
Classification: List A in IVDD annex II

Conformity Assessment Route: Annex IV.3 and IV.4

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, Germany

We hereby certify that the forgoing is a true and accurate statement.

Place, Date of Issue: Shenzhen, 2021-7-29



Signatory name: Wang Xinbing

Signatory Title: Manager of Technical Regulation Department

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Attachment I

Auto Hematology Analyzer, Semi-auto Chemistry Analyzer, Chemistry Analyzer,
 Chemiluminescence Immunoassay Analyzer, Sample Processing System:

No.	Model	Product Name
1	BC-6800	Auto Hematology Analyzer
2	CAL 6000	Auto Hematology Analyzer
3	BC-6200	Auto Hematology Analyzer
4	BC-6000	Auto Hematology Analyzer
5	BC-5390	Auto Hematology Analyzer
6	BC-5380	Auto Hematology Analyzer
7	BC-5300	Auto Hematology Analyzer
8	BC-5800	Auto Hematology Analyzer
9	CAL 8000	Sample Processing System
10	BC-7500[B] CRP	Auto Hematology Analyzer
11	BC-7500[N] CRP	Auto Hematology Analyzer
12	BC-7500[R] CRP	Auto Hematology Analyzer
13	BC-7500[NR] CRP	Auto Hematology Analyzer
14	BC-6800Plus	Auto Hematology Analyzer
15	BC-5000	Auto Hematology Analyzer
16	BC-5150	Auto Hematology Analyzer
17	BC-5390 CRP	Auto Hematology Analyzer
18	BA-88A	Semi-auto Chemistry Analyzer
19	BS-230	Chemistry Analyzer
20	BS-240	Chemistry Analyzer
21	BS-360E	Chemistry Analyzer
22	BS-240Pro	Chemistry Analyzer
23	BS-390	Chemistry Analyzer
24	BS-430	Chemistry Analyzer
25	BS-480	Chemistry Analyzer
26	BS-600	Chemistry Analyzer
27	BS-800	Chemistry Analyzer
28	BS-800M	Chemistry Analyzer
29	BS-2000	Chemistry Analyzer
30	BS-2000M	Chemistry Analyzer
31	CL-960i	Chemiluminescence Immunoassay Analyzer
32	CL-1200i	Chemiluminescence Immunoassay Analyzer
33	CL-2000i	Chemiluminescence Immunoassay Analyzer
34	SPL 1000	Sample Processing System
35	SPL 2000	Sample Processing System

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Reagents, Calibrators, and Controls for Auto Hematology Analyzer:

No.	Product name
1	M-68DS DILUENT
2	M-68DR DILUENT
3	M-68LD LYSE
4	M-68LN LYSE
5	M-68LB LYSE
6	M-68LH LYSE
7	M-68FN DYE
8	M-68FR DYE
9	M-68FD DYE
10	PROBE CLEANSER
11	DS DILUENT
12	M-6LD LYSE
13	M-6LN LYSE
14	M-6LH LYSE
15	M-6FN DYE
16	M-6FD DYE
17	M-6DR DILUENT
18	M-6FR DYE
19	M-58D DILUENT
20	M-58LEO(I) LYSE
21	M-58LEO(II) LYSE
22	M-58LH LYSE
23	M-58LBA LYSE
24	M-53D DILUENT
25	M-5 LEO(I) LYSE
26	M-5 LEO(II) LYSE
27	M-53 LH LYSE
28	LC LYSE
29	C-reactive Protein (CRP) Kit (Latex Immunoturbidimetric Method)
30	M-53LEO(I) LYSE
31	M-53LEO(II) LYSE
32	M-53LH LYSE
33	M-53 CLEANSER
34	M-52D DILUENT
35	M-52DIFF LYSE
36	M-52LH LYSE
37	M-30D DILUENT
38	M-30CFL LYSE
39	M-30R RINSE
40	M-30E E-Z CLEANSER
41	M-30P PROBE CLEANSER
42	M-10 CFL LYSE

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43	SC-CAL PLUS Hematology Calibrator
44	BC-3D Hematology Control
45	BC-5D Hematology Control
46	BC-6D Hematology Control
47	BC-RET Hematology Control
48	S30 Calibrator
49	S50 Calibrator
50	B30 Hematology Control
51	B55 Hematology Control
52	BC-BF Hematology Control

Consumables for Chemistry Analyzer:

No.	Product name
1	Reaction Cuvette for Chemistry Analyzer
2	CD80 Detergent

Reagents, Calibrators, and Controls for Chemistry Analyzer:

No.	Product name
1	Angiotensin Converting Enzyme Kit (Enzymatic Colorimetric Assay Method)
2	Adenosine Deaminase Kit (Enzymatic Colorimetric Method)
3	α -L-Fucosidase Kit (CNPf Method)
4	Albumin Kit (Bromocresol Green Method)
5	Alkaline Phosphatase Kit (IFCC Modified Method)
6	Alanine Aminotransferase Kit (IFCC Method)
7	α -Amylase Kit (IFCC Method)
8	Apolipoprotein A1 Kit (Turbidimetry Method)
9	Apolipoprotein B Kit (Turbidimetry Method)
10	Antistreptolysin "O" Kit (Latex Immunoturbidimetric Method)
11	Aspartate Aminotransferase Kit (IFCC Method)
12	β 2-Microglobulin Kit (Latex Immunoturbidimetric Method)
13	Complement C3 Kit (Turbidimetry Method)
14	Complement C4 Kit (Turbidimetry Method)
15	Calcium Kit (Arsenazo III Method)
16	Cholinesterase (CHE) Kit (DGKC Method)
17	Creatine Kinase Kit (IFCC Method)
18	Creatine Kinase-MB Kit (IFCC Method)
19	Carbon Dioxide (CO ₂) Kit (Enzymatic Method)
20	Creatinine Kit (Sarcosine Oxidase Method)
21	C-Reactive Protein Kit (Turbidimetry Method)

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22	Cystatin C Kit (Latex Immunoturbidimetric Method)
23	Bilirubin Direct Kit (DSA Method)
24	Bilirubin Direct Kit (VOX Method)
25	D-Dimer Kit (Particle-enhanced Immunoturbidimetric Assay Method)
26	β -Hydroxybutyrate Kit (Enzymatic Colorimetric Method)
27	Iron (Fe) Kit (Colorimetric Assay)
28	Ferritin Kit (Particle-enhanced Immunoturbidimetric Assay Method)
29	Full Range C-Reactive Protein Kit (Latex Immunoturbidimetric Method)
30	Fructosamine (FUN) Kit (Colorimetric Assay)
31	Gamma-Glutamyltransferase Kit (Szasz Method/IFCC stand)
32	Glucose Kit (GOD-POD Method)
33	Glucose Kit (HK Method)
34	Glucose-6-Phosphate Dehydrogenase Kit(UV Enzymatic Method)
35	Hemoglobin A1c Kit (Enzymatic Assay Method)
36	α -Hydroxybutyrate Dehydrogenase Kit (DGKC Method)
37	HDL-Cholesterol Kit (Direct Method)
38	High Sensitivity C-reaction Protein Kit (Particle-enhanced Immunoturbidimetric Assay Method)
39	Homocysteine (HCY) Kit (Enzymatic Cycling Method)
40	Immunoglobulin A Kit (Turbidimetry Method)
41	Immunoglobulin E Kit(Particle-enhanced Immunoturbidimetric Assay Method)
42	Immunoglobulin G Kit (Turbidimetry Method)
43	Immunoglobulin M Kit (Turbidimetry Method)
44	Lactate Dehydrogenase Kit (IFCC Method)
45	LDL-Cholesterol Kit (Direct Method)
46	Lipase Kit (Enzymatic Colorimetric Assay Method)
47	Lipoprotein (a) Kit (Latex Immunoturbidimetric Method)
48	Microalbumin Kit (Immunoturbidimetric Assay Method)
49	Magnesium Kit (Xylidyl Blue Method)
50	Myoglobin Kit (Particle-enhanced Immunoturbidimetric Assay Method)
51	Phosphorus Kit (Phosphomolybdate Method)
52	Prealbumin Kit (Turbidimetry Method)
53	Retinol Binding Protein Kit (Particle-enhanced Immunoturbidimetric Assay Method)
54	Rheumatoid Factor Kit (Immunoturbidimetric Method)
55	Total Bile Acids Kit (Enzymatic Cycling Assay)
56	Bilirubin Total Kit (DSA Method)
57	Bilirubin Total Kit (VOX Method)
58	Total Cholesterol Kit (CHOD-POD Method)
59	Triglycerides Kit (GPO-POD Method)
60	Total Protein Kit (Biuret Method)
61	Total Protein in Urine/CSF(TPUC)Kit (Pyrogallol Red-Molybdate Method)

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62	Transferrin Kit (Immunoturbidimetric Assay Method)
63	Uric Acid Kit (Uricase-Peroxidase Method)
64	Unsaturated Iron Binding Capacity Kit (Colorimetric Method)
65	Urea Kit (Urease-GLDH, UV Method)
66	Multi Sera Calibrator
67	Specific Proteins Calibrator
68	Prealbumin Calibrator
69	Lipids Calibrator
70	CK-MB Calibrator
71	MYO Calibrator
72	RBP Calibrator
73	UIBC Calibrator
74	IgE Calibrator
75	FER Calibrator
76	ACE Calibrator
77	MALB Calibrator
78	TRF Calibrator
79	β -HB Calibrator
80	HbA1c Calibrator
81	ADA Calibrator
82	C-reactive Protein Calibrator
83	Cystatin C Calibrator
84	β 2-Microglobulin Calibrator(for Serum)
85	β 2-Microglobulin Calibrator(for Urine)
86	Lipoprotein (a) Control
87	HbA1C Control P
88	HbA1C Control N
89	FUN Control P
90	D-Dimer Control
91	Multimmun Control
92	RBP Control
93	UIBC Control
94	G6PD Control
95	ACE Control
96	MALB Control
97	TRF Control
98	β -HB Control
99	TBA Control
100	ADA Control
101	AFU Control
102	ClinChem Multi Control(level 1)
103	ClinChem Multi Control(level 2)

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104	ASO/CRP/RF Triple Control
105	Cystatin C Control
106	β 2-Microglobulin Control
107	TPUC Control
108	HCY Control

Consumables for Chemiluminescence Immunoassay Analyzer:

No.	Product name
1	Reaction Cuvette for Chemiluminescence Immunoassay Analyzer
2	Substrate Solution
3	Wash Buffer
4	DETERGENT C
5	Waste Bin for Chemiluminescence Immunoassay Analyzer
6	Sample Diluent
7	System Wash Solution
8	System Detection Solution

Reagents, Calibrators, and Controls for Chemiluminescence Immunoassay Analyzer:

No.	Product name
1	Free Triiodothyronine (CLIA)
2	Free Thyroxine (CLIA)
3	Total Triiodothyronine (CLIA)
4	Total Thyroxine (CLIA)
5	Thyroid-Stimulating Hormone (CLIA)
6	Thyroglobulin (CLIA)
7	Antibody to thyroglobulin (CLIA)
8	Antibody to thyroid peroxidase (CLIA)
9	Cancer Antigen 125 (CLIA)
10	Carbohydrate Antigen 19-9 (CLIA)
11	Carcinoembryonic Antigen (CLIA)
12	Alpha-fetoprotein (CLIA)
13	Ferritin (CLIA)
14	Cancer Antigen 15-3 (CLIA)
15	Cancer Antigen 72-4 (CLIA)
16	Neuron-specific enolase (CLIA)
17	CYFRA 21-1 (CLIA)
18	Total β Human Chorionic Gonadotropin (CLIA)
19	Luteinizing Hormone (CLIA)
20	Follicle Stimulating Hormone (CLIA)
21	Prolactin (CLIA)

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22	Estriol(CLIA)
23	Progesterone(CLIA)
24	Testosterone(CLIA)
25	Estradiol(CLIA)
26	Dehydroepiandrosterone sulfate(CLIA)
27	Cortisol(CLIA)
28	Adrenocorticotrophic hormone(CLIA)
29	Insulin(CLIA)
30	C-peptide(CLIA)
31	Troponin I(CLIA)
32	Myoglobin(CLIA)
33	Creatine kinase MB(CLIA)
34	B-type natriuretic peptide(CLIA)
35	Antibody to Treponema Pallidum (CLIA)
36	25-OH-Vitamin D Total (CLIA)
37	Vitamin B12(CLIA)
38	Folate(CLIA)
39	Parathyroid hormone(CLIA)
40	Calcitonin(CLIA)
41	Reverse Triiodothyronine(CLIA)
42	Pepsinogen I (CLIA)
43	Pepsinogen II (CLIA)
44	Laminin(CLIA)
45	Hyaluronic Acid(CLIA)
46	N-terminal Peptide of Procollagen Type III(CLIA)
47	Collagen Type IV(CLIA)
48	Procalcitonin (CLIA)
49	Carbohydrate Antigen 50 (CLIA)
50	Carbohydrate Antigen 242(CLIA)
51	Human Epididymal Protein 4 (CLIA)
52	Squamous Cell Carcinoma Antigen (CLIA)
53	ProGRP (CLIA)
54	Total β Human Chorionic Gonadotropin (CLIA)
55	Anti-Mullerian Hormone(CLIA)
56	Red Blood Cell Folate Releasing Reagent
57	Procalcitonin(CLIA)
58	Aldosterone (CLIA)
59	Severe Acute Respiratory Syndrome Coronavirus 2 IgM (CLIA)
60	Severe Acute Respiratory Syndrome Coronavirus 2 IgG (CLIA)
61	Severe Acute Respiratory Syndrome Coronavirus 2 S-RBD IgG (CLIA)
62	Free T3 Calibrators
63	Free T4 Calibrators

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64	Total T3 Calibrators
65	Total T4 Calibrators
66	TSH Calibrators
67	Thyroglobulin Calibrators
68	Anti-Tg Calibrators
69	Anti-TPO Calibrators
70	CA125 Calibrators
71	CA19-9 Calibrators
72	CEA Calibrators
73	AFP Calibrators
74	Ferritin Calibrators
75	CA15-3 Calibrators
76	CA72-4 Calibrators
77	NSE Calibrators
78	CYFRA 21-1 Calibrators
79	Total β HCG Calibrators
80	LH Calibrators
81	FSH Calibrators
82	Prolactin Calibrators
83	Estriol Calibrators
84	Progesterone Calibrators
85	Testosterone Calibrators
86	Estradiol Calibrators
87	DHEA-S Calibrators
88	Cortisol Calibrators
89	ACTH Calibrators
90	Insulin Calibrators
91	C-Peptide Calibrators
92	Troponin I Calibrators
93	MYO Calibrators
94	CK-MB Calibrators
95	BNP Calibrators
96	Anti-TP Calibrators
97	PTH Calibrators
98	Calcitonin Calibrators
99	25-OH-Vitamin D Total Calibrators
100	Vitamin B12 Calibrators
101	Folate Calibrators
102	rT3 Calibrators
103	PG I Calibrators
104	PG II Calibrators
105	CA 50 Calibrators

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106	CA 242 Calibrators
107	HE-4 Calibrators
108	SCCA Calibrators
109	ProGRP Calibrators
110	PCT Calibrators
111	ALD Calibrators
112	Renin Calibrators
113	Thyroid Function Multi Control
114	Anti-thyroid Antibodies Control
115	Tumor Marker Multi Control
116	NSE Control
117	Reproductive Multi Control
118	ACTH Control
119	Immunoassay Multi Control
120	Cardiac Marker Multi Control
121	Anti-TP Positive Control
122	Anti-TP Negative Control
123	Metabolic Multi Control
124	AMH Control
125	rT3 Control
126	Gastritis Multi Control
127	Liver Fibrosis Multi Control
128	PCT Control
129	Tumor Marker Multi Control II
130	ProGRP Control
131	Hypertension Multi Control
132	SARS-CoV-2 IgM/IgG Negative Control
133	SARS-CoV-2 IgM Positive Control
134	SARS-CoV-2 IgG Positive Control
135	SARS-CoV-2 S-RBD IgG Antibody Control (L)
136	SARS-CoV-2 S-RBD IgG Antibody Control (H)

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Attachment II

Reagents, Calibrators, and Controls for Chemiluminescence Immunoassay Analyzer:

No.	Product name
1	Total Prostate Specific Antigen (CLIA)
2	Free Prostate Specific Antigen (CLIA)
3	Total PSA Calibrators
4	Free PSA Calibrators
5	Tumor Marker Multi Control

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Attachment III

Reagents, Calibrators, and Controls for Chemiluminescence Immunoassay Analyzer:

No.	Product name
1	Hepatitis B Surface Antigen (CLIA)
2	Antibody to Hepatitis B Surface Antigen (CLIA)
3	Hepatitis B e Antigen (CLIA)
4	Antibody to Hepatitis B e Antigen (CLIA)
5	Antibody to Hepatitis B Core Antigen (CLIA)
6	Antigen and Antibodies to Human Immunodeficiency Virus (CLIA)
7	HBsAg Calibrators
8	Anti-HBs Calibrators
9	HBeAg Calibrators
10	Anti-HBe Calibrators
11	Anti-HBc Calibrators
12	HIV Calibrators
13	HBsAg Positive Control
14	HBsAg Negative Control
15	Anti-HBs Positive Control
16	Anti-HBs Negative Control
17	HBeAg Positive Control
18	HBeAg Negative Control
19	Anti-HBe Positive Control
20	Anti-HBe Negative Control
21	Anti-HBc Positive Control
22	Anti-HBc Negative Control
23	HIV Ag/Ab Positive Control
24	HIV Ag/Ab Negative Control

Declaration of Conformity V1.0

Declaration of Conformity



Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co.,
Ltd.
Mindray Building, Keji 12th Road South, High-Tech Industrial
Park, Nanshan, 518057, Shenzhen, P. R. China

Manufacturer SRN: CN-MF-000014156

Authorized Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80 20537 Hamburg, Germany

Product: Chemiluminescence Immunoassay Analyzer

Model: CL-900i、CL-920i、CL-960i、CL-980i

Basic UDI-DI: 69449040MY YQ-BM50*****BZ

Intended Purpose: The instrument is an automated Analyzer for immunological
analysis. It is designed for determination of analytes in serum,
plasma and other human body fluids.

Classification: Class A (According to Rule 5 of IVDR annex VIII)

Conformity Assessment Route: Annex II and III of IVDR

GMDN code: 56701

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: /

Notified Body No. : /

Identification of the Certificate: /

Start of CE-Marking: 2018.10.17

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.



Zhejiang SKG Medical Technology Co., Ltd

Add: No.39, Anye Road, Gaoqiao Street, Huangyan, Taizhou, Zhejiang, China, 318020

Tel: 0086-576-84031666 Fax: 0086-576-84036668 Http://www.skgmed.com

CE Declaration of Conformity

Manufacturer: Zhejiang SKG Medical Technology Co., Ltd.

NO.39 Anye Road, Gaoqiao Street, Huangyan 318020 Taizhou, Zhejiang

PEOPLE'S REPUBLIC OF CHINA

European

Representative: Shanghai International Holding corp.GmbH(Europe)

Eiffestrabe 80 20537 Hamburg GERMANY

Product Name: Sample Cup

Model Number: BS-200, 700

Classification (IVDD): Other

Conformity Assessment Route: IVDD Annex III

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied:

ISO13485:2003, ISO11135-1:2007, ISO14971:2007, ISO 15223-1:2012

Notified Body: TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65·80339

München Germany

Identification number: Not applicable

(EC) Certificate(s): Not applicable

Expire date of the Certificate: Not applicable

Start of CE Marking: Not yet

Place, Date of Issue: HuangYan 2021-12-17

Signature: 

Name: Sujian

Position: General Manager

