

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

**Date: 07.02.2025**

**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, 2025**. 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,

  


Gao Xiufu  
Regional Sales & Marketing Manager, IVD Sales & Marketing Department, Central Asia  
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.





















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](http://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



**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:** See Attachment I

**Catalogue Number:** See Attachment I

**Classification:** See Attachment I

**Conformity Assessment Route:** Annex IX excluding CHAPTER II

**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:** TÜV SÜD Product Service GmbH Ridlerstraße 65  
80339 München, Germany.

**Notified Body No. :** 0123

**Identification of the Certificate:** NO. V12 044751 0190

**Start of CE-Marking:** 2022.8.25

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

**Place, Date of Issue:** Shenzhen, 2024.9.14

**Signature:**

**Name of Authorized Signatory:**

**Position Held in Company:**

Bobby Liu

Manager, Technical Regulation Department



**Attachment I**

**CLIA reagents and consumables**

<b>NO.</b>	<b>Product Name</b>	<b>Catalogue Number</b>	<b>Classification</b>
1	Free Triiodothyronine (CLIA)	105-004208-00 105-004235-00	Class B (According to Rule 6 of IVDR Annex VIII)
2	Free Thyroxine (CLIA)	105-004209-00 105-004236-00	Class B (According to Rule 6 of IVDR Annex VIII)
3	Total Triiodothyronine (CLIA)	105-004210-00 105-004237-00	Class B (According to Rule 6 of IVDR Annex VIII)
4	Total Thyroxine (CLIA)	105-004211-00 105-004238-00	Class B (According to Rule 6 of IVDR Annex VIII)
5	Thyroid-Stimulating Hormone (CLIA)	105-004212-00 105-004239-00	Class B (According to Rule 6 of IVDR Annex VIII)
6	Antibody to thyroglobulin(CLIA)	105-005664-00 105-005681-00	Class B (According to Rule 6 of IVDR Annex VIII)
7	Antibody to thyroid peroxidase(CLIA)	105-005665-00 105-005682-00	Class B (According to Rule 6 of IVDR Annex VIII)
8	Thyroglobulin(CLIA)	105-005663-00 105-005680-00	Class B (According to Rule 6 of IVDR Annex VIII)
9	Reverse Triiodothyronine (CLIA)	105-010692-00 105-010719-00	Class B (According to Rule 6 of IVDR Annex VIII)
10	Anti-Thyrotropin Receptor Antibody (CLIA)	105-010975-00 105-010976-00	Class B (According to Rule 6 of IVDR Annex VIII)
11	Total $\beta$ Human Chorionic Gonadotrophin II (CLIA)	105-017089-00 105-017090-00	Class B (According to Rule 6 of IVDR Annex VIII)
12	Follicle Stimulating Hormone (CLIA)	105-004222-00 105-004249-00	Class B (According to Rule 6 of IVDR Annex VIII)
13	Luteinizing Hormone (CLIA)	105-004223-00 105-004250-00	Class B (According to Rule 6 of IVDR Annex VIII)

14	Prolactin (CLIA)	105-004224-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-004251-00	
15	Estradiol (CLIA)	105-004225-00	Class B (According to Rule 6 of IVDR Annex VIII)
		105-004252-00	
16	Estriol (CLIA)	105-004253-00	Class B (According to Rule 6 of IVDR Annex VIII)
		105-004226-00	
17	Testosterone II (CLIA)	105-037228-00	Class B (According to Rule 6 of IVDR Annex VIII)
		105-037229-00	
18	Progesterone II (CLIA)	105-032072-00	Class B (According to Rule 6 of IVDR Annex VIII)
		105-032073-00	
19	Anti-Mullerian Hormone (CLIA)	105-010711-00	Class B (According to Rule 6 of IVDR Annex VIII)
		105-010738-00	
20	Carcinoembryonic Antigen (CLIA)	105-004213-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-004240-00	
21	Alpha fetoprotein (CLIA)	105-004214-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-004241-00	
22	Cancer Antigen 125(CLIA)	105-004215-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-004242-00	
23	Cancer Antigen 15-3(CLIA)	105-004216-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-004243-00	
24	Carbohydrate Antigen 19-9 (CLIA)	105-004217-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-004244-00	
25	Free Prostate Specific Antigen (CLIA)	105-004218-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-004245-00	
26	Total Prostate Specific Antigen(CLIA)	105-004219-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-004246-00	
27	Cancer Antigen 72-4(CLIA)	105-005668-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-005685-00	
28	Neuron-specific enolase(CLIA)	105-005669-00	Class C (According to Rule 3 of IVDR Annex VIII)



		105-005686-00	VIII)
29	CYFRA 21-1(CLIA)	105-005670-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-005687-00	
30	Pepsinogen I (CLIA)	105-010086-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-010096-00	
31	Pepsinogen II (CLIA)	105-010087-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-010097-00	
32	ProGRP (CLIA)	105-010084-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-010094-00	
33	Squamous Cell Carcinoma Antigen (CLIA)	105-010085-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-010095-00	
34	Human Epididymal Protein 4 (CLIA)	105-010088-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-010098-00	
35	Carbohydrate Antigen 242 (CLIA)	105-010089-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-010099-00	
36	Carbohydrate Antigen 50 (CLIA)	105-010090-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-010100-00	
37	Gastrin-17 (CLIA)	105-029892-00	Class B (According to Rule 6 of IVDR Annex VIII)
		105-029891-00	
38	PIVKA-II (CLIA)	105-029894-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-029895-00	
39	Parathyroid hormone(CLIA)	105-008684-00	Class B (According to Rule 6 of IVDR Annex VIII)
		105-008689-00	
40	Calcitonin(CLIA)	105-008685-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-008690-00	
41	25-OH-Vitamin D Total (CLIA)	105-008681-00	Class B (According to Rule 6 of IVDR Annex VIII)
		105-008686-00	
42	Troponin I(CLIA)	105-005659-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-005676-00	

43	B-type natriuretic peptide(CLIA)	105-005660-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-005677-00	
44	Myoglobin(CLIA)	105-005661-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-005678-00	
45	Creatine kinase MB(CLIA)	105-005662-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-005679-00	
46	N-terminal pro B-type natriuretic peptide (CLIA)	105-027044-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-027045-00	
47	High Sensitivity Cardiac Troponin I (CLIA)	105-028989-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-028988-00	
48	Insulin(CLIA)	105-005666-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-005683-00	
49	C-Peptide(CLIA)	105-005667-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-005684-00	
50	Cortisol(CLIA)	105-005673-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-005690-00	
51	Dehydroepiandrosterone sulfate(CLIA)	105-005674-00	Class B (According to Rule 6 of IVDR Annex VIII)
		105-005691-00	
52	Adrenocorticotrophic hormone(CLIA)	105-005675-00	Class B (According to Rule 6 of IVDR Annex VIII)
		105-005692-00	
53	Toxoplasma gondii IgM (CLIA)	105-012534-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-012533-00	
54	Toxoplasma gondii IgG (CLIA)	105-012527-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-012528-00	
55	Rubella Virus IgM (CLIA)	105-012515-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-012516-00	
56	Rubella Virus IgG (CLIA)	105-012521-00	Class C (According to Rule 3 of IVDR Annex VIII)
		105-012522-00	



57	Cytomegalovirus IgM (CLIA)	105-012545-00 105-012546-00	Class C (According to Rule 3 of IVDR Annex VIII)
58	Cytomegalovirus IgG (CLIA)	105-012539-00 105-012540-00	Class C (According to Rule 3 of IVDR Annex VIII)
59	Herpes Simplex Virus-1 IgG (CLIA)	105-012503-00 105-012504-00	Class C (According to Rule 3 of IVDR Annex VIII)
60	Herpes Simplex Virus-2 IgG (CLIA)	105-012509-00 105-012510-00	Class C (According to Rule 3 of IVDR Annex VIII)
61	Herpes Simplex Virus 1+2 IgM (CLIA)	105-012491-00 105-012492-00	Class C (According to Rule 3 of IVDR Annex VIII)
62	Herpes Simplex Virus 1+2 IgG (CLIA)	105-012497-00 105-012498-00	Class C (According to Rule 3 of IVDR Annex VIII)
63	Toxoplasma gondii IgG Avidity (CLIA)	105-029863-00 105-029867-00	Class C (According to Rule 3 of IVDR Annex VIII)
64	Cytomegalovirus IgG Avidity (CLIA)	105-029871-00 105-029870-00	Class C (According to Rule 3 of IVDR Annex VIII)
65	Procalcitonin(CLIA)	105-010703-00 105-010730-00	Class C (According to Rule 3 of IVDR Annex VIII)
66	sCD14-ST (CLIA)	105-023903-00 105-023902-00	Class C (According to Rule 3 of IVDR Annex VIII)
67	Aldosterone II (CLIA)	105-031481-00 105-029848-00	Class B (According to Rule 6 of IVDR Annex VIII)
68	Renin II (CLIA)	105-031483-00 105-031482-00	Class B (According to Rule 6 of IVDR Annex VIII)
69	Ferritin (CLIA)	105-004220-00 105-004247-00	Class C (According to Rule 3 of IVDR Annex VIII)
70	Vitamin B12(CLIA)	105-008682-00 105-008687-00	Class C (According to Rule 3 of IVDR Annex VIII)
71	Folate(CLIA)	105-008683-00	Class B (According to Rule 6 of IVDR Annex

		105-008688-00	VIII)
72	N-terminal Peptide of Procollagen Type III(CLIA)	105-010717-00 105-010744-00	Class B (According to Rule 6 of IVDR Annex VIII)
73	Collagen Type IV(CLIA)	105-010718-00 105-010745-00	Class B (According to Rule 6 of IVDR Annex VIII)
74	Laminin(CLIA)	105-010715-00 105-010742-00	Class B (According to Rule 6 of IVDR Annex VIII)
75	Hyaluronic Acid(CLIA)	105-010716-00 105-010743-00	Class B (According to Rule 6 of IVDR Annex VIII)
76	Human Growth Hormone (CLIA)	105-037749-00, 105-037750-00, 105-037732-00, 105-037733-00	Class B (According to Rule 6 of IVDR Annex VIII)
77	Insulin-like Growth Factor-1 (CLIA)	105-037773-00, 105-037772-00, 105-037747-00, 105-037748-00	Class B (According to Rule 6 of IVDR Annex VIII)
78	Free T3 Calibrators	105-004277-00	Class B (According to Rule 6 of IVDR Annex VIII)
79	Free T4 Calibrators	105-004278-00	Class B (According to Rule 6 of IVDR Annex VIII)
80	Total T3 Calibrators	105-004279-00	Class B (According to Rule 6 of IVDR Annex VIII)
81	Total T4 Calibrators	105-004280-00	Class B (According to Rule 6 of IVDR Annex VIII)
82	TSH Calibrators	105-004281-00	Class B (According to Rule 6 of IVDR Annex VIII)
83	Thyroglobulin Calibrators	105-005914-00	Class B (According to Rule 6 of IVDR Annex



			VIII)
84	Anti-Tg Calibrators	105-005915-00	Class B (According to Rule 6 of IVDR Annex VIII)
85	Anti-TPO Calibrators	105-005916-00	Class B (According to Rule 6 of IVDR Annex VIII)
86	rT3 Calibrators	105-010213-00	Class B (According to Rule 6 of IVDR Annex VIII)
87	Anti-Thyrotropin Receptor Antibody Calibrators	105-010214-00, 105-020852-00	Class B (According to Rule 6 of IVDR Annex VIII)
88	CEA Calibrators	105-004282-00	Class C (According to Rule 3 of IVDR Annex VIII)
89	AFP Calibrators	105-004283-00	Class C (According to Rule 3 of IVDR Annex VIII)
90	CA125 Calibrators	105-004284-00	Class C (According to Rule 3 of IVDR Annex VIII)
91	CA15-3 Calibrators	105-004285-00	Class C (According to Rule 3 of IVDR Annex VIII)
92	CA19-9 Calibrators	105-004286-00	Class C (According to Rule 3 of IVDR Annex VIII)
93	Free PSA Calibrators	105-004287-00	Class C (According to Rule 3 of IVDR Annex VIII)
94	Total PSA Calibrators	105-004288-00	Class C (According to Rule 3 of IVDR Annex VIII)
95	CA72-4 Calibrators	105-005919-00	Class C (According to Rule 3 of IVDR Annex VIII)
96	NSE Calibrators	105-005920-00	Class C (According to Rule 3 of IVDR Annex VIII)
97	CYFRA 21-1 Calibrators	105-005921-00	Class C (According to Rule 3 of IVDR Annex VIII)

98	PG I Calibrators	105-010136-00	Class C (According to Rule 3 of IVDR Annex VIII)
99	PG II Calibrators	105-010137-00	Class C (According to Rule 3 of IVDR Annex VIII)
100	ProGRP Calibrators	105-010134-00	Class C (According to Rule 3 of IVDR Annex VIII)
101	SCCA Calibrators	105-010135-00	Class C (According to Rule 3 of IVDR Annex VIII)
102	HE4 Calibrators	105-010138-00	Class C (According to Rule 3 of IVDR Annex VIII)
103	CA242 Calibrators	105-010139-00	Class C (According to Rule 3 of IVDR Annex VIII)
104	CA50 Calibrators	105-010140-00	Class C (According to Rule 3 of IVDR Annex VIII)
105	Gastrin-17 Calibrators	105-029893-00	Class B (According to Rule 6 of IVDR Annex VIII)
106	PIVKA-II Calibrators	105-029896-00	Class C (According to Rule 3 of IVDR Annex VIII)
107	Total $\beta$ HCG Calibrators	105-004290-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
108	FSH Calibrators	105-004291-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
109	LH Calibrators	105-004292-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
110	Prolactin Calibrators	105-004293-00	Class C (According to Rule 3 of IVDR Annex VIII)
111	Estradiol Calibrators	105-004296-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
112	Estriol Calibrators	105-004297-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)



			ANNEX VIII)
113	Testosterone Calibrators	105-004294-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
114	Progesterone Calibrators	105-004295-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
115	Insulin Calibrators	105-005917-00	Class C (According to Rule 3 of IVDR Annex VIII)
116	C-Peptide Calibrators	105-005918-00	Class C (According to Rule 3 of IVDR Annex VIII)
117	Cortisol Calibrators	105-005924-00	Class C (According to Rule 3 of IVDR Annex VIII)
118	DHEA-S Calibrators	105-005925-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
119	ACTH Calibrators	105-005926-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
120	Troponin I Calibrators	105-005910-00	Class C (According to Rule 3 of IVDR Annex VIII)
121	BNP Calibrators	105-005911-00	Class C (According to Rule 3 of IVDR Annex VIII)
122	MYO Calibrators	105-005912-00	Class C (According to Rule 3 of IVDR Annex VIII)
123	CK-MB Calibrators	105-005913-00	Class C (According to Rule 3 of IVDR Annex VIII)
124	NT-proBNP Calibrators	105-027049-00	Class C (According to Rule 3 of IVDR Annex VIII)
125	hs-cTnI Calibrators	105-031858-00	Class C (According to Rule 3 of IVDR Annex VIII)
126	Ferritin Calibrators	105-004289-00	Class C (According to Rule 3 of IVDR Annex VIII)

127	Vitamin B12 Calibrators	105-008552-00	Class C (According to Rule 3 of IVDR Annex VIII)
128	25-OH-Vitamin D Total Calibrators	105-008549-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
129	PTH Calibrators	105-008553-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
130	Calcitonin Calibrators	105-008550-00	Class C (According to Rule 3 of IVDR Annex VIII)
131	PCT Calibrators	105-010219-00	Class C (According to Rule 3 of IVDR Annex VIII)
132	sCD14-ST Calibrators	105-023905-00	Class C (According to Rule 3 of IVDR Annex VIII)
133	ALD Calibrators	105-011969-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
134	Renin Calibrators	105-012129-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
135	Thyroid Function Multi Control	105-007379-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
		105-007380-00	
		105-007371-00	
		105-007372-00	
136	Anti-thyroid Antibodies Control	105-005931-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
		105-005945-00	
		105-005932-00	
		105-005946-00	
		105-010221-00	
137	rT3 Control	105-010231-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
		105-010220-00	



		105-010240-00	
		105-010230-00	
		105-010250-00	
138	NSE control	105-005937-00 105-005951-00 105-005938-00 105-005952-00	Class C (According to Rule 3 of IVDR Annex VIII)
139	Gastritis Multi Control	105-010144-00 105-010154-00 105-010149-00 105-010159-00	Class C (According to Rule 3 of IVDR Annex VIII)
140	PIVKA-II control	105-031984-00 105-031983-00 105-031988-00 105-031987-00	Class C (According to Rule 3 of IVDR Annex VIII)
141	Tumor Marker Multi Control II	105-010146-00 105-010156-00 105-010151-00 105-010161-00	Class C (According to Rule 3 of IVDR Annex VIII)
142	ProGRP Control	105-010145-00 105-010155-00 105-010150-00 105-010160-00	Class C (According to Rule 3 of IVDR Annex VIII)
143	Reproductive Multi Control	105-008890-00 105-004266-00 105-008891-00	Class C (According to Rule 3 of IVDR Annex VIII)

		105-004267-00	
144	AMH Control	105-018808-00 105-018809-00 105-018810-00 105-018811-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
145	Cardiac Marker Multi Control	105-005941-00 105-005927-00 105-005942-00 105-005928-00	Class C (According to Rule 3 of IVDR Annex VIII)
146	hs-cTnI Control	105-031870-00 105-031861-00 105-031869-00 105-031860-00 105-031868-00 105-031856-00	Class C (According to Rule 3 of IVDR Annex VIII)
147	NT-proBNP Control	105-035649-00 105-035650-00 105-035738-00 105-035737-00	Class C (According to Rule 3 of IVDR Annex VIII)
148	Immunoassay Multi Control	105-005943-00 105-005929-00 105-005944-00 105-005930-00	Class C (According to Rule 3 of IVDR Annex VIII)
149	ACTH Control	105-005939-00 105-005953-00 105-005940-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)



		105-005954-00	
150	Metabolic Multi Control	105-008554-00 105-008556-00 105-008555-00 105-008557-00	Class C (According to Rule 3 of IVDR Annex VIII)
151	Liver Fibrosis Multi Control	105-010229-00 105-010249-00 105-010239-00 105-010259-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
152	PCT Control	105-010228-00 105-010248-00 105-010238-00 105-010258-00	Class C (According to Rule 3 of IVDR Annex VIII)
153	sCD14-ST Control	105-023924-00 105-023925-00 105-023932-00 105-023933-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
154	Hypertension Multi Control	105-012437-00 105-012438-00 105-012439-00 105-012440-00	CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII)
155	Toxo IgG Avidity Control	105-029872-00 105-029873-00 105-029874-00 105-029875-00 105-029876-00	Class C (According to Rule 3 of IVDR Annex VIII)

		105-029877-00	
		105-029878-00	
		105-029879-00	
156	CMV IgG Avidity Control	105-029880-00	C
		105-029881-00	
		105-029882-00	
		105-029883-00	
		105-029884-00	
		105-029885-00	
		105-029886-00	
		105-029887-00	





**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:** 69449040MYQQ-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

