

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

October 25, 2022

**LETTER OF AUTHORIZATION**

To whom it may concern,

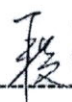
We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, (“**Mindray**”) manufacturer of **biochemical, imunological and coagulation analyzers, reagents and consumables** (“**Product(s)**”), hereby certify that “**Echipamed-Plus**” SRL, with business office at str. Valea Trandafirilor, 24B, of. 2-7, 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, 2023**. 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, CIS I Region  
**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**





REGISTRATION NO. 04721Q10132R7L

# CERTIFICATE OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of

**ShenZhenMindray Bio-Medical Electronics Co., Ltd.**

Registered Address: Floor 1st-Floor 4th, Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, Shenzhen, P.R.China

Manufacturing Address: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, Shenzhen, P.R.China; 1203 Nanhuan Avenue, Guangming District, Shenzhen, P. R. China

Has been assessed and conformed to the following standard(s)

**GB/T 19001-2016 idt ISO 9001:2015**

The certificate is valid for the following scope:

The Design, Development, Production and Service of Endoscope light source ,Diagnostic Ultrasound System , Endoscope Camera System, Microplate washer , UltraSync, patient monitor, Center Monitoring System, Telemetry Monitoring System, Vital Signs Monitor, Pulse Oximeter, Vital Signs Monitor & Patient Monitors, Disposable SpO2 Sensor, SpO2 Sensor, ECG Cable, NIBP Cuff, Temperature Probe, Holter, Wearable ECG Monitor, Analysis system, Defibrillator/Monitor, Electrocardiograph, Anesthesia Machine, Ventilator, Ultrasound Diagnostic System, Digital Ultrasonic Diagnostic Imaging System, Ultrasound Imaging Administration System, Digital Radiography System, Mobile radiography system, Mobile Stand, Radiography Imaging Information System, retropad detector and its imaging system, Auto Hematology Analyzer, Urine Apalyzer, Auto Silde Maker&Statiner, Flow Cytometer, Automatic Glycohemoglobin Analyzer, Specific Protein Analyzer, Sample Processing System, Chemistry Analyzer, Semi-auto Chemistry Analyzer, Microplate reader, Chemiluminescence Immunoassay Analyzer, CPR sensor, VS-900 Neo Vital Signs Monitor, Automated External Defibrillator, Ultrasonic Transducer, Automated Digital Cell Morphology Analyzer and Vitro Diagnostic Reagent (within the scope of manufacturing license)

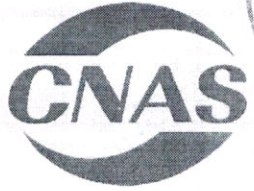
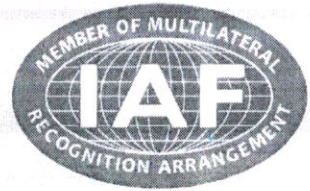
Date of issue: April 15, 2021

Date of expiry: April 05, 2024

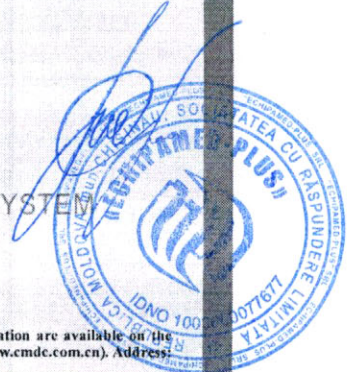
Date of change: May 31, 2022

General Manager:

**BEIJING HUA GUANG CERTIFICATION  
OF MEDICAL DEVICES CO., LTD.**



MANAGEMENT SYSTEM  
CNAS C047-M



Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (<http://www.cnca.gov.cn>) or the website of CMD (<http://www.cmdc.com.cn>). Address: 5<sup>th</sup> floor of Zhong Lian building, No. jia88, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993



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

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



# 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)

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**

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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

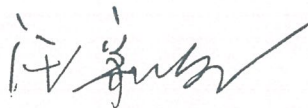
**Classification:** List A in IVDD annex II

**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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Fax: +86 755 26582680

## 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   | $\alpha$ -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   | $\alpha$ -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  | $\beta$ 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 <sub>2</sub> ) 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 | $\beta$ -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 | $\alpha$ -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  | $\beta$ -HB Calibrator                                      |
| 80  | HbA1c Calibrator  |
| 81  | ADA Calibrator  |
| 82  | C-reactive Protein Calibrator                               |
| 83  | Cystatin C Calibrator                                       |
| 84  | $\beta$ 2-Microglobulin Calibrator(for Serum)               |
| 85  | $\beta$ 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  | $\beta$ -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 | $\beta$ 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 $\beta$ 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 $\beta$ 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 $\beta$ 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:

| <b>No.</b> | <b>Product name</b>                    |
|------------|--|
| 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:

| <b>No.</b> | <b>Product name</b>   |
|------------|---|
| 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                                    |