Digitally signed by Iurchevici Valeriu
Date: 2025.07.04 17:38:23 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

CA-REGZ202502070014-1

mindray

"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.

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 81888998
Fax: +86 755 26582680
Website: www.mindray.com

ECHIPAMED-PLUS SOCIETATEA CU RASPUNDERE LIMITATA CHISINAU IDNO 1003600077677 REPUBLICA MOLDOVA

SCC Accredited CB-MS OCSM Accrédité OCN

TÜV SÜD America

CERTIFICATE

No. QS5 044751 0140 Rev. 05

Certificate Holder:

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:

TÜV SÜD ISO 9001

Scope of Certificate: See Page 2 for Overall Scope Statement.

Standard(s): ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: SH2305501

Effective Date: 2023-07-01

Expiry Date: 2026-06-30

Date of Issue: 2023-05-25

(Renee Walker)
Director, US Certification Body, MHS

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SCC Accredited CB-MS
OCSM Accrédité CCN

TÜV SÜD America

CERTIFICATE

No. QS5 044751 0140 Rev. 05

Overall Scope Statement:

Design and Development, Production and Distribution of Equipment (including 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 In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and 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, Wireless Module, Wireless Device

Date of Issue: 2023-05-25

(Renee Walker)
Director, US Certification Body, MHS

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TÜV®

CERTIFICATE

No. QS5 044751 0140 Rev. 05

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

Facility Scopes:

Design and Development, Production and Distribution of Equipment (including 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 In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and 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, Wireless Module, Wireless Device

Date of Issue: 2023-05-25

(Renee Walker)
Director, US Certification Body, MHS

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SCC Accredited CB-MS OCSM Accrédité CCN

TÜV SÜD America

CERTIFICATE

No. QS5 044751 0140 Rev. 05

Facility(ies):

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

Facility Scopes:

Design and Development, Production and Distribution of Equipment (including 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 In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and 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, Wireless Module, Wireless Device

Date of Issue: 2023-05-25

(Renee Walker)
Director, US Certification Body, MHS

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
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:

TÜV SÜD
EN ISO 13485
tuvsud.com/ps-cert

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

Christoph Dicks
Head of Certification/Notified Body

"TECHIPAMED-PLUS" IDNO 1003600077677

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
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 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
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.

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Declaration of Conformity V1.0

Declaration of Conformity

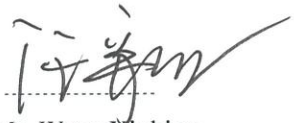
CE

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:	Chemistry Analyzer
Model:	BS-600M、BS-620M
Basic UDI-DI:	69449040SHYQ-BA6M******4T
Classification:	Class A (According to Rule 5 of IVDR annex VIII)
Conformity Assessment Route:	Annex II and III of IVDR
GMDN code:	56676

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:	**2022.3.25**

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, 2022.3.25
Signature:	
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Deputy Director, Technical Regulation Department

Attachment of Declaration of Conformity: Applied Standards List-V1.0

Applied Standards List

Product: Chemistry Analyzer

Model: BS-600M、BS-620M

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-3:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 61010-1:2010/A1:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN IEC 61010-2-081:2020	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
IEC 61010-2-101:2018	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

EN 61010-2-010:2020	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN61326-1:2021	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN61326-2-6:2021	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
BS ISO 20916:2019	In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice

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:	The products list as attachment
Classification:	The devices not in IVDD annex II and not for self testing/ performance evaluation
Conformity Assessment Route:	IVDD Annex III (excluding Section 6)

We declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

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, 2022.4.25
Signature:	Bai Yanhong
Name of Authorized Signatory:	Bai Yanhong
Position Held in Company:	Manager, Technical Regulation Department

Attachment of Declaration of Conformity: Products List

Products List

NO	Product Name	catalog number
1	Magnesium Kit (Xylidyl Blue Method)	105-000834-00
2		105-000873-00
3		105-001609-00
4	Bilirubin Direct Kit (DSA Method)	105-000851-00
5		105-000890-00
6		105-001626-00
7	Bilirubin Total Kit (DSA Method)	105-000850-00
8		105-000889-00
9		105-001625-00
10	Phosphorus Kit (Phosphomolybdate Method)	105-015573-00
11		105-015574-00
12		105-015575-00
13	Total Protein Kit (Biuret Method)	105-015586-00
14		105-015587-00
15		105-015588-00
16	Phosphorus Kit (Phosphomolybdate Method)	105-000833-00
17		105-000872-00
18		105-001608-00
19	Total Protein Kit (Biuret Method)	105-000823-00
20		105-000862-00
21		105-001598-00
22	Multi Sera Calibrator	105-001127-00
23	ClinChem Multi Control (level 1)	105-009117-00
24	ClinChem Multi Control (level 2)	105-009118-00
25	TRF control	105-002318-00
26	UIBC control	105-002307-00

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:	Class A (According to Rule 5 of IVDR Annex VIII)
Conformity Assessment Route:	Annex II and III of IVDR

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:	/

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,2025.6.23
Signature:	Bai Yanhong
Name of Authorized Signatory:	Bai Yanhong
Position Held in Company:	Manager, Technical Regulation Department

Attachment I

NO	Product Name	Catalogue Number
1	MR Buffer Solution	105-001688-00
2	MR Buffer Solution	105-036023-00
3	MR Detergent Solution	105-001692-00
4	MR Na/K Check Solution	105-001693-00
5	CD80 Detergent	105-035958-00
6	CD80 Detergent	105-000106-00
7	CD80 Detergent	105-000748-00
8	CD80 Detergent	105-000107-00
9	CD80 Detergent	105-011705-00

Declaration of Conformity

CE 0123

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

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,2025.6.23
Signature:	Bai Yanhong
Name of Authorized Signatory:	Bai Yanhong
Position Held in Company:	Manager, Technical Regulation Department

Attachment I

NO	Product Name	catalog number	Classification
1	Lipoprotein (a) Kit (Latex Immunoturbidimetric Method)	105-019437-00	B
2		105-019439-00	
3		105-019441-00	
4	Lipoprotein (a) Calibrator	105-026280-00	B
5	Lipoprotein (a) Control	105-019443-00	B
6	Total Cholesterol Kit (CHOD-POD Method)	105-000820-00	B
7		105-000859-00	
8		105-001595-00	
9	Triglycerides Kit (GPO-POD Method)	105-000821-00	B
10		105-000860-00	
11		105-001596-00	
12	Alkaline Phosphatase Kit (IFCC Modified Method)	105-000816-00	B
13		105-000855-00	
14		105-004593-00	
15	Albumin Kit (Bromcresol Green Method)	105-000822-00	B
16		105-000861-00	
17		105-001597-00	
18	α-Amylase Kit (IFCC Method)	105-000847-00	C
19		105-000886-00	
20		105-001622-00	
21	Bilirubin Direct Kit (VOX Method)	105-000827-00	C
22		105-000866-00	
23		105-004599-00	
24	Bilirubin Total Kit (VOX Method)	105-000826-00	C
25		105-000865-00	
26		105-004598-00	
27	Hemoglobin A1c Kit (Enzymatic Assay Method)	105-002165-00	C
28		105-002166-00	
29		105-002167-00	
30		105-009338-00	
31		105-005737-00	
32		105-005738-00	
33	HbA1c Calibrator	105-003680-00	C
34	HbA1c Control P	105-002138-00	C
35	HbA1c Control N	105-002140-00	C
36	Uric Acid Kit (Uricase-Peroxidase Method)	105-000848-00	B
37		105-000887-00	
38		105-001623-00	
39	Urea Kit (Urease-GLDH, UV Method)	105-000824-00	B
40		105-000863-00	

41		105-004597-00	
42	Calcium Kit (Arsenazo III Method)	105-000825-00	B
43		105-000864-00	
44		105-001600-00	
45	C-Reactive Protein Kit (Turbidimetry Method)	105-000841-00	C
46		105-000880-00	
47		105-004605-00	
48	Rheumatoid Factor Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-002159-00	B
49		105-002177-00	
50		105-002179-00	
51		105-002161-00	
52	RF Calibrator	105-003683-00	B
53	Antistreptolysin "O" Kit (Latex Immunoturbidimetric Method)	105-009291-00	B
54		105-004630-00	
55		105-004631-00	
56		105-007673-00	
57		105-007674-00	
58		105-007675-00	
59		105-044230-00	
60		105-044231-00	
61		105-044232-00	
62	Antistreptolysin "O" Calibrator	105-004644-00	B
63	Alanine Aminotransferase Kit (IFCC Method)	105-000814-00	B
64		105-000853-00	
65		105-004591-00	
66	Aspartate Aminotransferase Kit (IFCC Method)	105-000815-00	B
67		105-000854-00	
68		105-004592-00	
69	Creatine Kinase Kit (IFCC Method)	105-004615-00	B
70		105-000869-00	
71		105-004600-00	
72	Creatine Kinase-MB Kit (IFCC Method)	105-004616-00	C
73		105-000870-00	
74		105-004601-00	
75	CK-MB Calibrator	105-001132-00	C
76	Glucose Kit (HK Method)	105-000832-00	C
77		105-000871-00	
78		105-004609-00	
79	Rheumatoid Factor Kit (Immunoturbidimetric Method)	105-004632-00	B
80		105-004633-00	
81		105-004634-00	
82	Rheumatoid Factor Calibrator	105-004645-00	B
83		105-004618-00	B

84	Immunoglobulin A Kit (Turbidimetry Method)	105-000881-00	
85		105-001617-00	
86	Immunoglobulin M Kit (Turbidimetry Method)	105-000843-00	B
87		105-000882-00	
88		105-004606-00	
89	Immunoglobulin G Kit (Turbidimetry Method)	105-004619-00	B
90		105-000883-00	
91		105-001619-00	
92	HDL-Cholesterol Kit (Direct Method)	105-000835-00	B
93		105-000874-00	
94		105-004610-00	
95	LDL-Cholesterol Kit (Direct Method)	105-000836-00	B
96		105-000875-00	
97		105-004611-00	
98	Gamma-Glutamyltransferase Kit (Szasz Method/IFCC stand)	105-000817-00	B
99		105-000856-00	
100		105-004594-00	
101	Creatinine Kit (Sarcosine Oxidase Method)	105-004614-00	B
102		105-000868-00	
103		105-004612-00	
104	Total Protein in Urine/CSF(TPUC)Kit (Pyrogallol Red-Molybdate Method)	105-009168-00	B
105		105-009169-00	
106		105-009170-00	
107	TPUC Control	105-009193-00	B
108	High Sensitivity C-reaction Protein Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-001942-00	C
109		105-001943-00	
110		105-001944-00	
111		105-002201-00	
112		105-002202-00	
113		105-002203-00	
114	HS-CRP Calibrator	105-003685-00	C
115	Lactate Dehydrogenase Kit (IFCC Method)	105-000818-00	B
116		105-000857-00	
117		105-004595-00	
118	Transferrin Kit (Immunoturbidimetric Assay Method)	105-004507-00	B
119		105-006178-00	
120		105-006177-00	
121		105-002246-00	
122		105-004508-00	
123		105-002247-00	
124	TRF Calibrator	105-002317-00	B
125	Iron (Fe) Kit (Colorimetric Assay)	105-002198-00	B
126		105-002199-00	

127		105-002200-00	
128	Carbon Dioxide (CO2) Kit (Enzymatic Method)	105-002189-00	B
129		105-002190-00	
130		105-002191-00	
131	Complement C3 Kit (Turbidimetry Method)	105-004617-00	B
132		105-000878-00	
133		105-001614-00	
134	Complement C4 Kit (Turbidimetry Method)	105-000840-00	B
135		105-000879-00	
136		105-004604-00	
137	Apolipoprotein A1 Kit (Turbidimetry Method)	105-000837-00	B
138		105-000876-00	
139		105-004602-00	
140	Apolipoprotein B Kit (Turbidimetry Method)	105-000838-00	B
141		105-000877-00	
142		105-004603-00	
143	Ferritin Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-006175-00	C
144		105-006176-00	
145		105-002244-00	
146		105-002245-00	
147		105-004505-00	
148		105-004506-00	
149	FER Calibrator	105-002311-00	C
150	Microalbumin Kit (Immunoturbidimetric Assay Method)	105-006173-00	B
151		105-002242-00	
152		105-002243-00	
153		105-006174-00	
154		105-004503-00	
155		105-004504-00	
156	MALB Calibrator	105-002315-00	B
157	MALB Control	105-002316-00	B
158	α-Hydroxybutyrate Dehydrogenase Kit (DGKC Method)	105-000819-00	B
159		105-000858-00	
160		105-004596-00	
161	Total Bile Acids Kit (Enzymatic Cycling Assay)	105-000867-00	B
162		105-001603-00	
163		105-004613-00	
164	Lipase Kit (Enzymatic Colorimetric Assay Method)	105-002171-00	B
165		105-002172-00	
166		105-002173-00	
167	Fructosamine (FUN) Kit (Colorimetric Assay)	105-002195-00	B
168		105-002196-00	
169		105-002197-00	

170	FUN Control	105-020477-00	B
171	Immunoglobulin E Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-020854-00	B
172		105-004501-00	
173		105-004502-00	
174		105-020853-00	
175		105-002240-00	
176		105-002241-00	
177	IgE Calibrator	105-002309-00	B
178	D-Dimer Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-012738-00	C
179		105-002236-00	
180		105-002237-00	
181		105-012737-00	
182		105-004497-00	
183		105-004498-00	
184	D-Dimer Calibrator	105-002300-00	C
185	D-Dimer Control	105-002301-00	C
186	Homocysteine (HCY) Kit (Enzymatic Cycling Method)	105-009174-00	B
187		105-009175-00	
188		105-009176-00	
189	HCY Control	105-009194-00	B
190	Adenosine Deaminase Kit (Enzymatic Colorimetric Method)	105-003177-00	B
191		105-003120-00	
192		105-003125-00	
193		105-026284-00	
194		105-026285-00	
195		105-026286-00	
196	ADA Calibrator	105-003687-00	B
197	ADA Control	105-020473-00	B
198	Unsaturated Iron Binding Capacity Kit (Colorimetric Method)	105-009265-00	B
199		105-004515-00	
200		105-004516-00	
201	UIBC Calibrator	105-002306-00	B
202	Retinol Binding Protein Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-009269-00	B
203		105-002250-00	
204		105-002251-00	
205		105-006182-00	
206		105-004511-00	
207		105-004512-00	
208	RBP Calibrator	105-002304-00	B
209	RBP Control	105-002305-00	B
210	Angiotensin Converting Enzyme Kit (Enzymatic Colorimetric Assay Method)	105-006179-00	B
211		105-002248-00	
212		105-002249-00	

213		105-006180-00	
214		105-004509-00	
215		105-004510-00	
216	ACE Calibrator	105-002313-00	B
217	ACE Control	105-002314-00	B
218	5'-Nucleotidase Kit (Enzymatic Colorimetric Method)	105-003176-00	B
219		105-003119-00	
220		105-003124-00	
221		105-026281-00	
222		105-026282-00	
223		105-026283-00	
224	5'-NT Calibrator	105-003688-00	B
225	5'-NT Control	105-020475-00	B
226	Glucose-6-Phosphate Dehydrogenase Kit (UV Enzymatic Method)	105-009264-00	C
227		105-002254-00	
228		105-002255-00	
229	G6PD Control	105-002308-00	C
230	β-Hydroxybutyrate Kit (Enzymatic Colorimetric Method)	105-006184-00	B
231		105-004513-00	
232		105-004514-00	
233	β-HB Calibrator	105-002319-00	B
234	β-HB Control	105-002320-00	B
235	α-L-Fucosidase Kit (CNPF Method)	105-003180-00	C
236		105-003123-00	
237		105-003128-00	
238	AFU Control	105-020474-00	C
239	Cholinesterase (CHE) Kit (DGKC Method)	105-002162-00	B
240		105-002163-00	
241		105-002164-00	
242	Cystatin C Kit (Latex Immunoturbidimetric Method)	105-004638-00	B
243		105-004639-00	
244		105-004640-00	
245	Cystatin C Calibrator	105-004647-00	B
246	Cystatin C Control	105-004651-00	B
247	Myoglobin Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-012736-00	C
248		105-002238-00	
249		105-002239-00	
250		105-012735-00	
251		105-004499-00	
252		105-004500-00	
253	MYO Calibrator	105-002302-00	C
254	Prealbumin Kit (Turbidimetry Method)	105-000845-00	B
255		105-000884-00	

256		105-004607-00	
257	Prealbumin Calibrator	105-001130-00	B
258	Glucose Kit (GOD-POD Method)	105-000849-00	C
259		105-000888-00	
260		105-001624-00	
261	β2-Microglobulin Kit (Latex Immunoturbidimetric Method)	105-004641-00	B
262		105-004642-00	
263		105-004643-00	
264	β2-Microglobulin Calibrator(for Serum)	105-004648-00	B
265	β2-Microglobulin Calibrator(for Urine)	105-004649-00	B
266	β2-Microglobulin Control	105-004652-00	B
267	Multi Sera Calibrator	105-001144-00	C
268	Specific Proteins Calibrator	105-001129-00	C
269	Lipids Calibrator	105-001128-00	B
270	Multimmun control	105-002303-00	C
273	ClinChem Multi Control (level 1)	105-009119-00	C
274	ClinChem Multi Control (level 2)	105-009120-00	C
275	ASO/CRP/RF Triple Control	105-004650-00	C
276	CO2 and TBA Multi Control	105-020476-00	B
277	MR Serum Standard	105-001689-00	B
278	MR Urine Standard	105-001690-00	B
279	MR Urine Quality Control	105-001691-00	B
280	Chloride Electrode	040-000542-00	B
281	Potassium Electrode	040-000541-00	B
282	Reference Electrode	040-000539-00	B
283	Sodium Electrode	040-000540-00	B
284	Chloride Electrode	115-084091-00	B
285	Potassium Electrode	115-084089-00	B
286	Reference Electrode	115-084088-00	B
287	Sodium Electrode	115-084090-00	B

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

PEOLPLE'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

ZHEJIANG SKG MEDICAL TECHNOLOGY CO.,LTD. 浙江双康医疗科技有限公司

MECHIPAMED-PLUS

EC DECLARATION OF CONFORMITY
According to Art.17 of Regulation 2017/746 (EU) on In Vitro Diagnostic Medical Devices

ARCHEM SAĞLIK SANAYİ VE TİCARET ANONİM ŞİRKETİ

SRN : TR-MF-000027166

Address : MAHMUTBEY MH. HALKALI CD. NO:124/42 BAĞCILAR İSTANBUL TÜRKİYE

Tel : + 90 212 444 08 92

Faks : +90 212 629 98 89

E-mail : info@archem.com.tr

Product Information

Product Name	:	CD80 DETERGENT
Brand Name	:	ARCHEM
Classification	:	Class A, according to Rule 5 of IVDR Annex VIII
Basic UDI-DI	:	**869901528AR00LM**

Conformity Assessment: The conformity of the determined product to the In Vitro Diagnostic Medical Devices Regulation (EU)2017/746 was evaluated by issuing the EU declaration of conformity referred to in Article 17, after the technical documents specified in Annex-IV (Annex II and III) were prepared.

This declaration of conformity is the responsibility of our company.

We declare that the above-mentioned products meet the requirements of the in Vitro Diagnostic Medical Device regulation (EU) 2017/746 and the applicable standards above.

List of Directive and Standard Applied:
EN ISO 20417: 2021
EN ISO 15223-1:2016
EN ISO 18113-1:2011
EN ISO 14971:2019
EN ISO 13485:2016

CE

Published by: ERKAN UCA (General Manager)

Publication Date: 15.08.2022
Published in: İstanbul

archem SAĞLIK SAN. VE TİC. ANONİM ŞTİ. Bağcılar/İSTANBUL

.....
Stamp/Signature

Rev. No 01

EC DECLARATION OF CONFORMITY
According to Art.17 of Regulation 2017/746 (EU) on In Vitro Diagnostic Medical Devices

ARCHEM SAĞLIK SANAYİ VE TİCARET ANONİM ŞİRKETİ

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Faks : +90 212 629 98 89

E-mail : info@archem.com.tr

Product Information

Product Name	:	PROBE CLEANSER
Brand Name	:	ARCHEM
Classification	:	Class A, according to Rule 5 of IVDR Annex VIII
Basic UDI-DI	:	**869901528AR00LM**

Conformity Assessment: The conformity of the determined product to the In Vitro Diagnostic Medical Devices Regulation (EU)2017/746 was evaluated by issuing the EU declaration of conformity referred to in Article 17, after the technical documents specified in Annex-IV (Annex II and III) were prepared.

This declaration of conformity is the responsibility of our company.

We declare that the above-mentioned products meet the requirements of the in Vitro Diagnostic Medical Device regulation (EU) 2017/746 and the applicable standards above.

List of Directive and Standard Applied:
EN ISO 20417: 2021
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EN ISO 14971:2019
EN ISO 13485:2016

CE

Published by: **ERKAN UCA (General Manager)**

Publication Date: **15.08.2022**
Published in: **İstanbul**

archem
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Stamp/Signature

Rev. No **01**

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CONFORMITY DECLARATION CE

With a full responsibility, we declare that products:

water purification systems (demineralizers) – models: ***HLP SMART, HLP 5, HLP 5S, HLP 5P, HLP 5SP, HLP 5UV, HLP 10, HLP 10S, HLP 10P, HLP 10SP, HLP 10UV, HLP 20P, HLP 20S, HLP 20SP, HLP 20UV, HLP 30P, HLP 30S, HLP 30SP, HLP 30UV, HLP 40***

fit the requirements of directives listed below:

- low-voltage electric device (LVD) No 2014/35/EU

- electromagnetic compatibility (EMC) No 2014/30/EU

- on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS II) 2011/65 / EU

Evaluation was performed by using harmonized standards:

• PN-EN 61010 Wymagania bezpieczeństwa dotyczące elektrycznych przyrządów do pomiarów, sterowania i użytku z laboratoriach.
• PN-EN 61326 Wyposażenie elektryczne do pomiarów, sterowania i użytku w laboratoriach. Wymagania dotyczące kompatybilności elektromagnetycznej (EMC),
• PN-EN 62311 Ocena sprzętu elektronicznego i elektrycznego związana z ograniczeniami narażania ludzi na działanie pól elektromagnetycznych (0 Hz - 300 GHz)
• PN-EN 50581 Dokumentacja techniczna oceny wyrobów elektrycznych i elektronicznych z uwzględnieniem ograniczenia stosowania substancji niebezpiecznych

Last two digits of the year, when the CE was issued: 14.

Date: 02/01/2021

Przemysław Ganczarek

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NIP 604-006-82-97 KRS 0000392441

REPUBLICA MOLDOVA mun. CHISINAU, SOCIETATEA CU RASPUNDERE LIMITATA "ECHIPAMED-PLUS" IDNO 1003600077677