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

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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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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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

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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

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
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,2024.12.11
Signature:	
Name of Authorized Signatory:	Bobby Liu
Position Held in Company:	Manager, Technical Regulation Department

Attachment I

NO	Product Name	Catalogue Number	Classification
1	Lipoprotein (a) Kit (Latex Immunoturbidimetric Method)	105-019437-00	Class B (According to Rule 6 of IVDR Annex VIII)
2		105-019439-00	
3		105-019441-00	
4	Lipoprotein (a) Control	105-019443-00	Class B (According to Rule 6 of IVDR Annex VIII)
5	Total Cholesterol Kit (CHOD-POD Method)	105-000820-00	Class B (According to Rule 6 of IVDR Annex VIII)
6		105-000859-00	
7		105-001595-00	
8	Triglycerides Kit (GPO-POD Method)	105-000821-00	Class B (According to Rule 6 of IVDR Annex VIII)
9		105-000860-00	
10		105-001596-00	
11	Alkaline Phosphatase Kit (IFCC Modified Method)	105-000816-00	Class B (According to Rule 6 of IVDR Annex VIII)
12		105-000855-00	
13		105-004593-00	
14	Albumin Kit (Bromcresol Green Method)	105-000822-00	Class B (According to Rule 6 of IVDR Annex VIII)
15		105-000861-00	
16		105-001597-00	
17	α-Amylase Kit (IFCC Method)	105-000847-00	Class C (According to Rule 3 of IVDR Annex VIII)
18		105-000886-00	
19	Bilirubin Direct Kit (VOX Method)	105-000827-00	Class C (According to Rule 3 of IVDR Annex VIII)
20		105-000866-00	
21		105-004599-00	
22	Bilirubin Total Kit (VOX Method)	105-000826-00	Class C (According to Rule 3 of IVDR Annex VIII)
23		105-000865-00	
24		105-004598-00	
25	HbA1c Calibrator	105-003680-00	Class C (According to Rule 3 of IVDR Annex VIII)
26	HbA1c Control P	105-002138-00	Class C (According to Rule 3 of IVDR Annex VIII)
27	HbA1c Control N	105-002140-00	Class C (According to Rule 3 of IVDR Annex VIII)
28	Uric Acid Kit (Uricase-Peroxidase Method)	105-000887-00	Class B (According to Rule 6 of IVDR Annex VIII)

29	Urea Kit (Urease-GLDH, UV Method)	105-000824-00	Class B (According to Rule 6 of IVDR Annex VIII)
30		105-000863-00	
31		105-004597-00	
32	Phosphorus Kit (Phosphomolybdate Method)	105-000833-00	Class B (According to Rule 6 of IVDR Annex VIII)
33		105-000872-00	
34		105-001608-00	
35	Calcium Kit (Arsenazo III Method)	105-000825-00	Class B (According to Rule 6 of IVDR Annex VIII)
36		105-000864-00	
37		105-001600-00	
38	C-Reactive Protein Kit (Turbidimetry Method)	105-000841-00	Class C (According to Rule 3 of IVDR Annex VIII)
39		105-000880-00	
40		105-004605-00	
41	Rheumatoid Factor Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-002179-00	Class B (According to Rule 6 of IVDR Annex VIII)
42		105-002161-00	
43	RF Calibrator	105-003683-00	Class B (According to Rule 6 of IVDR Annex VIII)
44	Antistreptolysin "O" Kit (Latex Immunoturbidimetric Method)	105-009291-00	Class B (According to Rule 6 of IVDR Annex VIII)
45		105-004630-00	
46		105-004631-00	
47		105-007673-00	
48		105-007674-00	
49		105-007675-00	
50	Antistreptolysin "O" Calibrator	105-004644-00	Class B (According to Rule 6 of IVDR Annex VIII)
51	Alanine Aminotransferase Kit (IFCC Method)	105-000814-00	Class B (According to Rule 6 of IVDR Annex VIII)
52		105-000853-00	
53		105-004591-00	
54	Aspartate Aminotransferase Kit (IFCC Method)	105-000815-00	Class B (According to Rule 6 of IVDR Annex VIII)
55		105-000854-00	
56		105-004592-00	
57	Creatine Kinase Kit (IFCC Method)	105-004615-00	Class B (According to Rule 6 of IVDR Annex VIII)
58		105-000869-00	
59		105-004600-00	
60	Creatine Kinase-MB Kit (IFCC Method)	105-004616-00	Class C (According to Rule 3 of IVDR Annex VIII)
61		105-000870-00	
62		105-004601-00	
63	CK-MB Calibrator	105-001132-00	Class C (According to Rule 3 of IVDR Annex VIII)

64	Glucose Kit (HK Method)	105-000832-00	Class C (According to Rule 3 of IVDR Annex VIII)
65		105-000871-00	
66		105-004609-00	
67	Rheumatoid Factor Kit (Immunoturbidimetric Method)	105-004632-00	Class B (According to Rule 6 of IVDR Annex VIII)
68		105-004633-00	
69		105-004634-00	
70	Rheumatoid Factor Calibrator	105-004645-00	Class B (According to Rule 6 of IVDR Annex VIII)
71	Immunoglobulin A Kit (Turbidimetry Method)	105-004618-00	Class B (According to Rule 6 of IVDR Annex VIII)
72		105-000881-00	
73		105-001617-00	
74	Immunoglobulin M Kit (Turbidimetry Method)	105-000843-00	Class B (According to Rule 6 of IVDR Annex VIII)
75		105-000882-00	
76		105-004606-00	
77	Immunoglobulin G Kit (Turbidimetry Method)	105-004619-00	Class B (According to Rule 6 of IVDR Annex VIII)
78		105-000883-00	
79		105-001619-00	
80	HDL-Cholesterol Kit (Direct Method)	105-000835-00	Class B (According to Rule 6 of IVDR Annex VIII)
81		105-000874-00	
82		105-004610-00	
83	LDL-Cholesterol Kit(Direct Method)	105-000836-00	Class B (According to Rule 6 of IVDR Annex VIII)
84		105-000875-00	
85		105-004611-00	
86	Gamma-Glutamyltransferase Kit (Szasz Method/IFCC stand)	105-000817-00	Class B (According to Rule 6 of IVDR Annex VIII)
87		105-000856-00	
88		105-004594-00	
89	Creatinine Kit (Sarcosine Oxidase Method)	105-004614-00	Class B (According to Rule 6 of IVDR Annex VIII)
90		105-000868-00	
91		105-004612-00	
92	Total Protein Kit (Biuret Method)	105-000823-00	Class B (According to Rule 6 of IVDR Annex VIII)
93	Total Protein in Urine/CSF(TPUC)Kit (Pyrogallol Red-Molybdate Method)	105-009168-00	Class B (According to Rule 6 of IVDR Annex VIII)
94		105-009169-00	
95		105-009170-00	
96	TPUC Control	105-009193-00	Class B (According to Rule 6 of IVDR Annex VIII)
97	High Sensitivity C-reaction Protein Kit (Particle-enhanced	105-001942-00	Class C (According to Rule 3 of IVDR Annex VIII)
98		105-001943-00	
99		105-001944-00	

	Immunoturbidimetric Assay Method)		
100	HS-CRP Calibrator	105-003685-00	Class C (According to Rule 3 of IVDR Annex VIII)
101	Urea Kit (Urease-GLDH, UV Method)	105-000818-00	Class B (According to Rule 6 of IVDR Annex VIII)
102		105-000857-00	
103		105-004595-00	
104	Transferrin Kit (Immunoturbidimetric Assay Method)	105-004507-00	Class B (According to Rule 6 of IVDR Annex VIII)
105		105-006178-00	
106		105-006177-00	
107		105-002246-00	
108		105-004508-00	
109		105-002247-00	
110	TRF Calibrator	105-002317-00	Class B (According to Rule 6 of IVDR Annex VIII)
111	Iron (Fe) Kit (Colorimetric Assay)	105-002198-00	Class B (According to Rule 6 of IVDR Annex VIII)
112		105-002199-00	
113	Carbon Dioxide (CO2) Kit (Enzymatic Method)	105-002190-00	Class B (According to Rule 6 of IVDR Annex VIII)
114		105-002191-00	
115	Complement C3 Kit (Turbidimetry Method)	105-004617-00	Class B (According to Rule 6 of IVDR Annex VIII)
116		105-000878-00	
117		105-001614-00	
118	Complement C4 Kit (Turbidimetry Method)	105-000840-00	Class B (According to Rule 6 of IVDR Annex VIII)
119		105-000879-00	
120		105-004604-00	
121	Apolipoprotein A1 Kit (Turbidimetry Method)	105-000837-00	Class B (According to Rule 6 of IVDR Annex VIII)
122		105-000876-00	
123		105-004602-00	
124	Apolipoprotein B Kit (Turbidimetry Method)	105-000838-00	Class B (According to Rule 6 of IVDR Annex VIII)
125		105-000877-00	
126		105-004603-00	
127	Ferritin Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-006175-00	Class C (According to Rule 3 of IVDR Annex VIII)
128		105-006176-00	
129		105-002244-00	
130		105-002245-00	
131		105-004505-00	
132		105-004506-00	

133	FER Calibrator	105-002311-00	Class C (According to Rule 3 of IVDR Annex VIII)
134	Microalbumin Kit (Immunoturbidimetric Assay Method)	105-006173-00	Class B (According to Rule 6 of IVDR Annex VIII)
135		105-002242-00	
136		105-002243-00	
137		105-006174-00	
138		105-004503-00	
139		105-004504-00	
140	MALB Calibrator	105-002315-00	Class B (According to Rule 6 of IVDR Annex VIII)
141	MALB Control	105-002316-00	Class B (According to Rule 6 of IVDR Annex VIII)
142	α-Hydroxybutyrate Dehydrogenase Kit (DGKC Method)	105-000819-00	Class B (According to Rule 6 of IVDR Annex VIII)
143		105-000858-00	
144		105-004596-00	
145	Total Bile Acids Kit (Enzymatic Cycling Assay)	105-000867-00	Class B (According to Rule 6 of IVDR Annex VIII)
146		105-001603-00	
147		105-004613-00	
148	Lipase Kit (Enzymatic Colorimetric Assay Method)	105-002171-00	Class B (According to Rule 6 of IVDR Annex VIII)
149		105-002172-00	
150		105-002173-00	
151	Fructosamine (FUN) Kit (Colorimetric Assay)	105-002195-00	Class B (According to Rule 6 of IVDR Annex VIII)
152		105-002196-00	
153	FUN Control	105-020477-00	Class B (According to Rule 6 of IVDR Annex VIII)
154	Immunoglobulin E Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-020854-00	Class B (According to Rule 6 of IVDR Annex VIII)
155		105-004501-00	
156		105-004502-00	
157		105-020853-00	
158		105-002240-00	
159		105-002241-00	
160	IgE Calibrator	105-002309-00	Class B (According to Rule 6 of IVDR Annex VIII)
161	D-Dimer Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-012738-00	Class C (According to Rule 3 of IVDR Annex VIII)
162		105-002236-00	
163		105-002237-00	
164		105-012737-00	

165		105-004497-00	
166		105-004498-00	
167	D-Dimer Calibrator	105-002300-00	Class C (According to Rule 3 of IVDR Annex VIII)
168	D-Dimer Control	105-002301-00	Class C (According to Rule 3 of IVDR Annex VIII)
169	Homocysteine (HCY) Kit (Enzymatic Cycling Method)	105-009174-00	Class B (According to Rule 6 of IVDR Annex VIII)
170		105-009175-00	
171		105-009176-00	
172	HCY Control	105-009194-00	Class B (According to Rule 6 of IVDR Annex VIII)
173	Adenosine Deaminase Kit (Enzymatic Colorimetric Method)	105-003177-00	Class B (According to Rule 6 of IVDR Annex VIII)
174		105-003120-00	
175		105-003125-00	
176		105-026284-00	
177		105-026285-00	
178		105-026286-00	
179	ADA Calibrator	105-003687-00	Class B (According to Rule 6 of IVDR Annex VIII)
180	ADA Control	105-020473-00	Class B (According to Rule 6 of IVDR Annex VIII)
181	Unsaturated Iron Binding Capacity Kit (Colorimetric Method)	105-009265-00	Class B (According to Rule 6 of IVDR Annex VIII)
182		105-004515-00	
183		105-004516-00	
184	UIBC Calibrator	105-002306-00	Class B (According to Rule 6 of IVDR Annex VIII)
185	Retinol Binding Protein Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-009269-00	Class B (According to Rule 6 of IVDR Annex VIII)
186		105-002250-00	
187		105-002251-00	
188		105-006182-00	
189		105-004511-00	
190		105-004512-00	
191	RBP Calibrator	105-002304-00	Class B (According to Rule 6 of IVDR Annex VIII)

192	RBP Control	105-002305-00	Class B (According to Rule 6 of IVDR Annex VIII)
193	Angiotensin Converting Enzyme Kit (Enzymatic Colorimetric Assay Method)	105-006179-00	Class B (According to Rule 6 of IVDR Annex VIII)
194		105-002248-00	
195		105-002249-00	
196		105-006180-00	
197		105-004509-00	
198		105-004510-00	
199	ACE Calibrator	105-002313-00	Class B (According to Rule 6 of IVDR Annex VIII)
200	ACE Control	105-002314-00	Class B (According to Rule 6 of IVDR Annex VIII)
201	5'-Nucleotidase Kit (Enzymatic Colorimetric Method)	105-003119-00	Class B (According to Rule 6 of IVDR Annex VIII)
202		105-003124-00	
203		105-026281-00	
204		105-026282-00	
205		105-026283-00	
206	5'-NT Calibrator	105-003688-00	Class B (According to Rule 6 of IVDR Annex VIII)
207	5'-NT Control	105-020475-00	Class B (According to Rule 6 of IVDR Annex VIII)
208	Glucose-6-Phosphate Dehydrogenase Kit (UV Enzymatic Method)	105-009264-00	Class C (According to Rule 3 of IVDR Annex VIII)
209		105-002254-00	
210		105-002255-00	
211	G6PD Control	105-002308-00	Class C (According to Rule 3 of IVDR Annex VIII)
212	β-Hydroxybutyrate Kit (Enzymatic Colorimetric Method)	105-006184-00	Class B (According to Rule 6 of IVDR Annex VIII)
213		105-004513-00	
214		105-004514-00	
215	β-HB Calibrator	105-002319-00	Class B (According to Rule 6 of IVDR Annex VIII)
216	β-HB Control	105-002320-00	Class B (According to Rule 6 of IVDR Annex VIII)
217		105-003123-00	

218	α-L-Fucosidase Kit (CNPF Method)	105-003128-00	Class C (According to Rule 3 of IVDR Annex VIII)
219	AFU Control	105-020474-00	Class C (According to Rule 3 of IVDR Annex VIII)
220	Cholinesterase (CHE) Kit (DGKC Method)	105-002162-00	Class B (According to Rule 6 of IVDR Annex VIII)
221		105-002163-00	
222	Cystatin C Kit (Latex Immunoturbidimetric Method)	105-004638-00	Class B (According to Rule 6 of IVDR Annex VIII)
223		105-004639-00	
224		105-004640-00	
225	Cystatin C Calibrator	105-004647-00	Class B (According to Rule 6 of IVDR Annex VIII)
226	Cystatin C Control	105-004651-00	Class B (According to Rule 6 of IVDR Annex VIII)
227	Myoglobin Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-012736-00	Class C (According to Rule 3 of IVDR Annex VIII)
228		105-002238-00	
229		105-002239-00	
230		105-012735-00	
231		105-004499-00	
232		105-004500-00	
233	MYO Calibrator	105-002302-00	Class C (According to Rule 3 of IVDR Annex VIII)
234	Prealbumin Kit (Turbidimetry Method)	105-000845-00	Class B (According to Rule 6 of IVDR Annex VIII)
235		105-000884-00	
236		105-004607-00	
237	Prealbumin Calibrator	105-001130-00	Class B (According to Rule 6 of IVDR Annex VIII)
238	Glucose Kit (GOD-POD Method)	105-000888-00	Class C (According to Rule 3 of IVDR Annex VIII)
239	β2-Microglobulin Kit (Latex Immunoturbidimetric Method)	105-004641-00	Class B (According to Rule 6 of IVDR Annex VIII)
240		105-004642-00	
241		105-004643-00	
242	β2-Microglobulin Calibrator(for Serum)	105-004648-00	Class B (According to Rule 6 of IVDR Annex VIII)

243	β2-Microglobulin Calibrator(for Urine)	105-004649-00	Class B (According to Rule 6 of IVDR Annex VIII)
244	β2-Microglobulin Control	105-004652-00	Class B (According to Rule 6 of IVDR Annex VIII)
245	Multi Sera Calibrator	105-001144-00	Class C (According to Rule 3 of IVDR Annex VIII)
246	Specific Proteins Calibrator	105-001129-00	Class C (According to Rule 3 of IVDR Annex VIII)
247	Lipids Calibrator	105-001128-00	Class B (According to Rule 6 of IVDR Annex VIII)
248	Multimmun control	105-002303-00	Class C (According to Rule 3 of IVDR Annex VIII)
249	ClinChem Multi Control (level 1)	105-009119-00	Class C (According to Rule 3 of IVDR Annex VIII)
250	ClinChem Multi Control (level 2)	105-009120-00	Class C (According to Rule 3 of IVDR Annex VIII)
251	ASO/CRP/RF Triple Control	105-004650-00	Class C (According to Rule 3 of IVDR Annex VIII)
252	CO2 and TBA Multi Control	105-020476-00	Class B (According to Rule 6 of IVDR Annex VIII)
253	Hemoglobin A1c Kit (Enzymatic Assay Method)	105-009338-00	Class C (According to Rule 3 of IVDR Annex VIII)
254		105-002167-00	
255		105-005738-00	

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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

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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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TECHIPAMED-PROS" IDNO 1003600077677