

GA-REGZ202601250001

**mindray**

“Echipamed-Plus” SRL  
str. Valea Trandafirilor, 24B, of. 2-7  
MD-2001, Chisinau, Moldova  
+373 22 234-349  
Date: 25.01.2026

**LETTER OF AUTHORIZATION**

To whom it may concern,

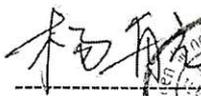
We, Shenzhen Mindray Bio-Medical Electronics Co., Ltd., (“Mindray”) manufacturer of biochemical, immunological and coagulation analyzers, reagents and consumables (“Product(s)”), hereby certify that “Echipamed-Plus” SRL, with business office at str. Valea Trandafirilor, 24B, of. 2-7, MD-2001, Chisinau, 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, 2026**. 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,

  
Yang Hang  
General Manager of Sales and Marketing Division, Central Asia Region III

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Date: 25.01.2026

**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













Product Service

# Certificate

No. Q5 044751 0164 Rev. 05

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

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

**Certification Mark:**



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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 044751 0164 Rev. 05](http://www.tuvsud.com/ps-cert?q=cert:Q5_044751_0164_Rev_05)

**Report No.:** SH2305501

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

**Date,** 2023-06-19

*C. Dicks*

Christoph Dicks  
 Head of Certification/Notified Body





# 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



## 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)

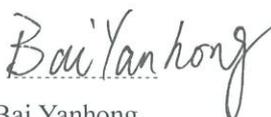
**We declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the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

**Name of Authorized Signatory:** Bai Yanhong

**Position Held in Company:** Manager, Technical Regulation Department

## Attachment of Declaration of Conformity: Products List

**Products List**

<b>NO</b>	<b>Product Name</b>	<b>catalog number</b>
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:**

**Name of Authorized Signatory:**

Bai Yanhong

**Position Held in Company:**

Manager, Technical Regulation Department

**Attachment I**

<b>NO</b>	<b>Product Name</b>	<b>Catalogue Number</b>
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

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## Declaration of Conformity



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

**Manufacturer SRN:** CN-MF-000014156

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

**Product:** See Attachment I

**Catalogue Number:** See Attachment I

**Classification:** See Attachment I

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

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

**References to CS:** /

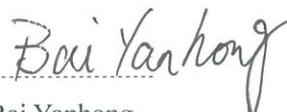
**Notified Body:** TÜV SÜD Product Service GmbH Ridlerstraße 65  
80339 München, Germany.

**Notified Body No. :** 0123

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

**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:** 

**Name of Authorized Signatory:** Bai Yanhong

**Position Held in Company:** Manager, Technical Regulation Department

**Attachment I**

<b>NO</b>	<b>Product Name</b>	<b>catalog number</b>	<b>Classification</b>
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	$\alpha$ -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	$\alpha$ -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	$\beta$ -Hydroxybutyrate Kit (Enzymatic Colorimetric Method)	105-006184-00	B
231		105-004513-00	
232		105-004514-00	
233	$\beta$ -HB Calibrator	105-002319-00	B
234	$\beta$ -HB Control	105-002320-00	B
235	$\alpha$ -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	$\beta$ 2-Microglobulin Kit (Latex Immunoturbidimetric Method)	105-004641-00	B
262		105-004642-00	
263		105-004643-00	
264	$\beta$ 2-Microglobulin Calibrator(for Serum)	105-004648-00	B
265	$\beta$ 2-Microglobulin Calibrator(for Urine)	105-004649-00	B
266	$\beta$ 2-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



**HYDROLAB**

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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.

*Przemysław Ganczarek*

Date: 02/01/2021

Przemysław Ganczarek





Product Service

# Certificate

No. Q5 042464 0033 Rev. 07

**Holder of Certificate:** **Zhejiang Gongdong Medical Technology Co., Ltd.**  
 No.10 Beiyuan Ave., Huangyan  
 318020 Taizhou, Zhejiang  
 PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development Production and Distribution of Non-active Medical Devices and IVD Consumables for Sample Collection and Transportation (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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 042464 0033 Rev. 07](http://www.tuvsud.com/ps-cert?q=cert:Q5 042464 0033 Rev. 07)

**Report No.:** SH24011102

**Valid from:** 2025-03-01

**Valid until:** 2028-02-28

**Date,** 2025-02-11

Christoph Dicks  
 Head of Certification/Notified Body





# Certificate

No. Q5 042464 0033 Rev. 07

**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):** **Zhejiang Gongdong Medical Technology Co., Ltd.**  
No.10 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang,  
PEOPLE'S REPUBLIC OF CHINA

Non-active Medical Devices:  
Design and Development, Production and Distribution of Plastic  
Pipette Tips, Plastic Forceps, Plastic First Aid Cases, Disposable  
Vaginal Speculum, Disposable Sterile Swabs For Sample  
Collection, Transportation Swabs with Medium, Disposable  
Umbilical Cord Scissors, Needle Holder, Disposable Anoscope,  
Disposable Loop Stick, Sterile Vaginal Applicator,  
Unicirc(Universal Circumcision Device), Sampling Scoops,  
Disposable Otoscope Tips(Ear Specula), Medical Isolation Face  
Shield, Medical Isolation Goggles, Oral Drug Delivery Devices,  
Mucus Trap, Ear Curette, Plastic Funnel, Urine Collection Kit.  
IVD Consumables for Sample Collection and Transportation:  
Design and Development, Production and Distribution of Plastic  
Centrifuge Tubes, Plastic Culture Dishes, Plastic Test Tubes,  
Plastic Sample Cups, Disposable Specimen Container, Plastic  
Storage Bottles, Culture Plate, Urine Sediment Counting Board,  
Embedding Cassette, Plastic Transfer Pipette, Cell Culture Flask,  
Sterile Erlenmeyer Flasks, Urine Transfer Straw.

**Zhejiang Gongdong Medical Technology Co., Ltd.**  
No.39 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang,  
PEOPLE'S REPUBLIC OF CHINA

Non-active Medical Devices:  
Design and Development, Production and Distribution of Plastic  
Pipette Tips, Plastic Forceps, Plastic First Aid Cases, Needle  
Holder, Disposable Anoscope, Disposable Loop Stick, Sampling  
Scoops, Disposable Otoscope Tips (Ear Specula), Saliva  
Collection Kit, Medical Isolation Face Shield, Medical Isolation  
Goggles, Mucus Trap, Ear Curette, Plastic Funnel, Suction  
Canister Kit.  
IVD Consumables for Sample Collection and Transportation:  
Design and Development, Production and Distribution of Plastic  
Centrifuge Tubes, Plastic Culture Dishes, Plastic Test Tubes,  
Plastic Sample Cups, Plastic Storage Bottles, Culture Plate, Urine  
Sediment Counting Board, Embedding Cassette, Plastic Transfer  
Pipette, Cell Culture Flask, Cell Factory, Serological Pipettes.



**Zhejiang Gongdong Medical Technology Co., Ltd.**  
No. 88 Jingxian Road, Huangyan, 318020 Taizhou, Zhejiang,  
PEOPLE'S REPUBLIC OF CHINA

Non-active Medical Devices:



Product Service

# Certificate

No. Q5 042464 0033 Rev. 07

Design and Development, Production and Distribution of Plastic Pipette Tips, Plastic Forceps, Plastic First Aid Cases, Disposable Vaginal Speculum, Disposable Sterile Swabs For Sample Collection, Transportation Swabs with Medium, Vacuum Urine Collection Sets, Disposable Umbilical Cord Scissors, Needle Holder, Disposable Anoscope, Disposable Loop Stick, Sterile Vaginal Applicator, Unicirc (Universal Circumcision Device), Sampling Scoops, Disposable Otoscope Tips (Ear Specula), Disposable Aqueous Humor Collector, Saliva Collection Kit, Medical Isolation Face Shield, Medical Isolation Goggles, Virus Collection and Preservation System, Oral Drug Delivery Device, Mucus Trap, Ear Curette, PRF Tubes, Plastic Funnel, Urine Collection Kit, Specimen Bag, Mouth Piece for Endoscopes, Disposable Vaginometer.

IVD Consumables for Sample Collection and Transportation: Design and Development, Production and Distribution of Plastic Centrifuge Tubes, Plastic Culture Dishes, Plastic Sample Cups, Plastic Test Tubes, Plastic Transfer Pipette, Disposable Vacuum Blood Tubes, Micro Blood Collection Tubes, Capillary Blood Collection Tubes, Disposable Specimen Container, Disposable Non Vacuum Blood Tubes, Plastic Storage Bottles, Culture Plate, Urine Sediment Counting Board, Serological Pipettes, Embedding Cassette, Cell Culture Flask, Cell Factory, Urine Transfer Straw, Disposable Urine Collection Tube.

J.

