

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,

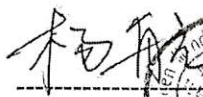
We, Shenzhen Mindray Bio-Medical Electronics Co., Ltd., (“Mindray”) manufacturer of biochemical, immunological and coagulation analyzers, reagents and consumables (“Product(s)”), hereby certify that “Echipamed-Plus” SRL, with business office at str. Valea Trandafirilor, 24B, of. 2-7, MD-2001, Chisinau,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

Report No.: SH2305501

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

Date, 2023-06-19

C. Dicks

Christoph Dicks
 Head of Certification/Notified Body





Product Service

Certificate

No. Q5 044751 0164 Rev. 05

Applied Standard(s): EN ISO 13485:2016
 Medical devices - Quality management systems -
 Requirements for regulatory purposes
 (ISO 13485:2016)
 DIN EN ISO 13485:2016

Facility(ies): **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**
 Mindray Building, Keji 12th Road South, High-Tech Industrial Park,
 Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

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

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

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





Certificate

No. Q5 044751 0164 Rev. 05

For the product(s)/product category (ies):

Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor , Defibrillator/Monitor and Accessories, Electrocardiograph, Anesthesia Machine and accessories, Ventilator, Air compressor, Endoscope Camera System, Endoscope Light Source and accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for invitro diagnostic use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker&Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer , Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer.



Declaration of Conformity



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

Manufacturer SRN: CN-MF-000014156

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

Product: See Attachment I

Catalogue Number: See Attachment I

Classification: See Attachment I

Conformity Assessment Route: Annex IX excluding CHAPTER II

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

References to CS: /

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

Notified Body No. : 0123

Identification of the Certificate: NO. V12 044751 0190

Start of CE-Marking: 2022.8.25

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

Place, Date of Issue: Shenzhen, 2024.12.11

Signature:

Name of Authorized Signatory:

Position Held in Company:



Bobby Liu

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 (Bromocresol 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	β 2-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	β 2-Microglobulin Calibrator(for Serum)	105-004648-00	Class B (According to Rule 6 of IVDR Annex VIII)

243	β 2-Microglobulin Calibrator(for Urine)	105-004649-00	Class B (According to Rule 6 of IVDR Annex VIII)
244	β 2-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	



Declaration of Conformity



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

Manufacturer SRN: CN-MF-000014156

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

Product: See Attachment I

Catalogue Number: See Attachment I

Classification: See Attachment I

Conformity Assessment Route: Annex IX excluding CHAPTER II

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

References to CS: /

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

Notified Body No. : 0123

Identification of the Certificate: NO. V12 044751 0190

Start of CE-Marking: 2022.8.25

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

Place, Date of Issue: Shenzhen, 2024.9.14

Signature:

Name of Authorized Signatory:

Position Held in Company:

Bobby Liu

Manager, Technical Regulation Department

Attachment I

CLIA reagents and consumables

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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
ISTANBUL 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



Published by: ERKAN UCA (General Manager)

Publication Date: 15.08.2022
Published in: İstanbul

Rev. No 01


SAĞLIK SANAYİ VE TİCARET ANONİM Şİ. No:124/42
Bağcılar/İS...+90 212 629 98 89
Stamp/Signature

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 : 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
EN ISO 15223-1:2016
EN ISO 18113-1:2011
EN ISO 14971:2019
EN ISO 13485:2016



Published by: ERKAN UCA (General Manager)

Publication Date: 15.08.2022
Published in: İstanbul

Rev. No 01


SAĞLIK SANAYİ VE TİCARET ANONİM ŞTİ.
Mahmutbey Mh. Halkalı Cd. No:124/42
Bağcılar/İSTANBUL T.C. 08 92 444 08 92
Güneşli V.D.:0730790980

Stamp/Signature