

“Echipamed-Plus” SRL

str. Valea Trandafirilor, 24B, of. 2-7 MD-2001, Chisinau, Moldova

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December 27th, 2024

MANUFACTURER’S LETTER OF AUTHORIZATION

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (“Mindray”)**, manufacturer of bidding products (“**Authorized Product(s)**”) as set forth in the below:

Product names	Product models
Reagents for biochemistry analyzers BS-800 and BS-620	/

hereby authorize **“Echipamed Plus” SRL** with business office at str. Valea Trandafirilor, 24B, of. 2-7, MD-2001, Chisinau, Republic of Moldova to submit a bid only for Tender (Tender no. **21322183**) (“**Tender**”) organized by **IMSP SCM Sf. Treime (“Procuring Entity”)** in **Moldova**. Nothing stated in this Manufacturer’s Letter of Authorization shall be understood, interpreted and construed as authorization of Distributor to negotiate and sign any contract or Tender document on behalf of and/or in the name of Mindray or any of Mindray’s affiliates. For sake of clarity, Distributor’s authorization is limited to:

- a) obtain Tender documents and prepare the Tender proposal;
- b) introduce, demonstrate, clarify and explain Authorized Product(s) as well as submit and clarify pertinent relevant information (including relevant Mindray company information) to Procuring Entity.

As the manufacturer, Mindray warrants that the Authorized Product(s) are free from defects in materials and workmanship, and provide warranty for the Authorized Products based on the standard Mindray’s warranty policy.



Neither this Manufacturer's Letter of Authorization nor any further extension, will impose any obligation or grant any rights regarding further distribution of the Authorized Product(s), nor allow any party to seek compensation for direct and/or consequential damages and losses (including without limitation to losses of goodwill, losses of business opportunities, etc.) developed during the term of Manufacturer's Letter of Authorization or any further extension.

Subject to applicable public tender laws and regulations and mandatory statutory requirements stated in Tender document, this Manufacturer's Authorization Letter takes effect as of **December 27th, 2024** and shall expire and terminate immediately upon the occurrence of any of the following events: (i) revocation of this Manufacturer's Authorization Letter in a fifteen (15) days prior written notice by Mindray at its sole discretion without any compensation to Distributor; (ii) the proposal, bid or offer for Tender by Distributor being rejected by the Procuring Entity; (iii) the Tender being awarded to other bidders; (iv) the Tender is invalidated or abolished for whatever reason. Distributor shall not sub-delegate, authorize all or any of the powers, authorities vested in it herein.

Sincerely yours,





Duan Liang

General Manager of Sales and Marketing Division, Central Asia
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Dated on December 27, 2024





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



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE



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.





DECLARATION OF CONFORMITY

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, located at Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA, hereby confirm that:

We herewith declare that the products listed in Attachment I, Attachment II, Attachment III meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices.

Product Category I : Auto Hematology Analyzer, Semi-auto Chemistry Analyzer, Chemistry Analyzer, Chemiluminescence Immunoassay Analyzer, Sample Processing System, Reagents, Calibrators, and Controls for Auto Hematology Analyzer, Consumables for Chemistry Analyzer, Reagents, Calibrators, and Controls for Chemistry Analyzer, Consumables for Chemiluminescence Immunoassay Analyzer, Reagents, Calibrators, and Controls for Chemiluminescence Immunoassay Analyzer

Products: Attachment I

Classification: The device not in IVDD annex II and not for self-testing/performance evaluation

Conformity Assessment Route: IVDD Annex III (not includes Section 6)

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Keji 12th Road South, High-Tech Industrial Park,

Nanshan, 518057 Shenzhen, P. R. China

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Product Category II: Reagents, Calibrators, and Controls for Chemiluminescence

Immunoassay Analyzer

Products: Attachment II

Classification: List B in IVDD annex II

Conformity Assessment Route: Annex IV.3

Product Category III: Reagents, Calibrators, and Controls for Chemiluminescence

Immunoassay Analyzer

Products: Attachment III

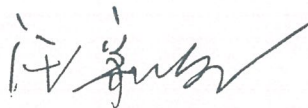
Classification: List A in IVDD annex II

Conformity Assessment Route: Annex IV.3 and IV.4

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

We hereby certify that the forgoing is a true and accurate statement.

Place, Date of Issue: Shenzhen, 2021-7-29



Signatory name: Wang Xinbing

Signatory Title: Manager of Technical Regulation Department

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Attachment I

Auto Hematology Analyzer, Semi-auto Chemistry Analyzer, Chemistry Analyzer,
 Chemiluminescence Immunoassay Analyzer, Sample Processing System:

No.	Model	Product Name
1	BC-6800	Auto Hematology Analyzer
2	CAL 6000	Auto Hematology Analyzer
3	BC-6200	Auto Hematology Analyzer
4	BC-6000	Auto Hematology Analyzer
5	BC-5390	Auto Hematology Analyzer
6	BC-5380	Auto Hematology Analyzer
7	BC-5300	Auto Hematology Analyzer
8	BC-5800	Auto Hematology Analyzer
9	CAL 8000	Sample Processing System
10	BC-7500[B] CRP	Auto Hematology Analyzer
11	BC-7500[N] CRP	Auto Hematology Analyzer
12	BC-7500[R] CRP	Auto Hematology Analyzer
13	BC-7500[NR] CRP	Auto Hematology Analyzer
14	BC-6800Plus	Auto Hematology Analyzer
15	BC-5000	Auto Hematology Analyzer
16	BC-5150	Auto Hematology Analyzer
17	BC-5390 CRP	Auto Hematology Analyzer
18	BA-88A	Semi-auto Chemistry Analyzer
19	BS-230	Chemistry Analyzer
20	BS-240	Chemistry Analyzer
21	BS-360E	Chemistry Analyzer
22	BS-240Pro	Chemistry Analyzer
23	BS-390	Chemistry Analyzer
24	BS-430	Chemistry Analyzer
25	BS-480	Chemistry Analyzer
26	BS-600	Chemistry Analyzer
27	BS-800	Chemistry Analyzer
28	BS-800M	Chemistry Analyzer
29	BS-2000	Chemistry Analyzer
30	BS-2000M	Chemistry Analyzer
31	CL-960i	Chemiluminescence Immunoassay Analyzer
32	CL-1200i	Chemiluminescence Immunoassay Analyzer
33	CL-2000i	Chemiluminescence Immunoassay Analyzer
34	SPL 1000	Sample Processing System
35	SPL 2000	Sample Processing System

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Reagents, Calibrators, and Controls for Auto Hematology Analyzer:

No.	Product name
1	M-68DS DILUENT
2	M-68DR DILUENT
3	M-68LD LYSE
4	M-68LN LYSE
5	M-68LB LYSE
6	M-68LH LYSE
7	M-68FN DYE
8	M-68FR DYE
9	M-68FD DYE
10	PROBE CLEANSER
11	DS DILUENT
12	M-6LD LYSE
13	M-6LN LYSE
14	M-6LH LYSE
15	M-6FN DYE
16	M-6FD DYE
17	M-6DR DILUENT
18	M-6FR DYE
19	M-58D DILUENT
20	M-58LEO(I) LYSE
21	M-58LEO(II) LYSE
22	M-58LH LYSE
23	M-58LBA LYSE
24	M-53D DILUENT
25	M-5 LEO(I) LYSE
26	M-5 LEO(II) LYSE
27	M-53 LH LYSE
28	LC LYSE
29	C-reactive Protein (CRP) Kit (Latex Immunoturbidimetric Method)
30	M-53LEO(I) LYSE
31	M-53LEO(II) LYSE
32	M-53LH LYSE
33	M-53 CLEANSER
34	M-52D DILUENT
35	M-52DIFF LYSE
36	M-52LH LYSE
37	M-30D DILUENT
38	M-30CFL LYSE
39	M-30R RINSE
40	M-30E E-Z CLEANSER
41	M-30P PROBE CLEANSER
42	M-10 CFL LYSE

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43	SC-CAL PLUS Hematology Calibrator
44	BC-3D Hematology Control
45	BC-5D Hematology Control
46	BC-6D Hematology Control
47	BC-RET Hematology Control
48	S30 Calibrator
49	S50 Calibrator
50	B30 Hematology Control
51	B55 Hematology Control
52	BC-BF Hematology Control

Consumables for Chemistry Analyzer:

No.	Product name
1	Reaction Cuvette for Chemistry Analyzer
2	CD80 Detergent

Reagents, Calibrators, and Controls for Chemistry Analyzer:

No.	Product name
1	Angiotensin Converting Enzyme Kit (Enzymatic Colorimetric Assay Method)
2	Adenosine Deaminase Kit (Enzymatic Colorimetric Method)
3	α -L-Fucosidase Kit (CNPf Method)
4	Albumin Kit (Bromocresol Green Method)
5	Alkaline Phosphatase Kit (IFCC Modified Method)
6	Alanine Aminotransferase Kit (IFCC Method)
7	α -Amylase Kit (IFCC Method)
8	Apolipoprotein A1 Kit (Turbidimetry Method)
9	Apolipoprotein B Kit (Turbidimetry Method)
10	Antistreptolysin "O" Kit (Latex Immunoturbidimetric Method)
11	Aspartate Aminotransferase Kit (IFCC Method)
12	β 2-Microglobulin Kit (Latex Immunoturbidimetric Method)
13	Complement C3 Kit (Turbidimetry Method)
14	Complement C4 Kit (Turbidimetry Method)
15	Calcium Kit (Arsenazo III Method)
16	Cholinesterase (CHE) Kit (DGKC Method)
17	Creatine Kinase Kit (IFCC Method)
18	Creatine Kinase-MB Kit (IFCC Method)
19	Carbon Dioxide (CO ₂) Kit (Enzymatic Method)
20	Creatinine Kit (Sarcosine Oxidase Method)
21	C-Reactive Protein Kit (Turbidimetry Method)

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22	Cystatin C Kit (Latex Immunoturbidimetric Method)
23	Bilirubin Direct Kit (DSA Method)
24	Bilirubin Direct Kit (VOX Method)
25	D-Dimer Kit (Particle-enhanced Immunoturbidimetric Assay Method)
26	β -Hydroxybutyrate Kit (Enzymatic Colorimetric Method)
27	Iron (Fe) Kit (Colorimetric Assay)
28	Ferritin Kit (Particle-enhanced Immunoturbidimetric Assay Method)
29	Full Range C-Reactive Protein Kit (Latex Immunoturbidimetric Method)
30	Fructosamine (FUN) Kit (Colorimetric Assay)
31	Gamma-Glutamyltransferase Kit (Szasz Method/IFCC stand)
32	Glucose Kit (GOD-POD Method)
33	Glucose Kit (HK Method)
34	Glucose-6-Phosphate Dehydrogenase Kit(UV Enzymatic Method)
35	Hemoglobin A1c Kit (Enzymatic Assay Method)
36	α -Hydroxybutyrate Dehydrogenase Kit (DGKC Method)
37	HDL-Cholesterol Kit (Direct Method)
38	High Sensitivity C-reaction Protein Kit (Particle-enhanced Immunoturbidimetric Assay Method)
39	Homocysteine (HCY) Kit (Enzymatic Cycling Method)
40	Immunoglobulin A Kit (Turbidimetry Method)
41	Immunoglobulin E Kit(Particle-enhanced Immunoturbidimetric Assay Method)
42	Immunoglobulin G Kit (Turbidimetry Method)
43	Immunoglobulin M Kit (Turbidimetry Method)
44	Lactate Dehydrogenase Kit (IFCC Method)
45	LDL-Cholesterol Kit (Direct Method)
46	Lipase Kit (Enzymatic Colorimetric Assay Method)
47	Lipoprotein (a) Kit (Latex Immunoturbidimetric Method)
48	Microalbumin Kit (Immunoturbidimetric Assay Method)
49	Magnesium Kit (Xylidyl Blue Method)
50	Myoglobin Kit (Particle-enhanced Immunoturbidimetric Assay Method)
51	Phosphorus Kit (Phosphomolybdate Method)
52	Prealbumin Kit (Turbidimetry Method)
53	Retinol Binding Protein Kit (Particle-enhanced Immunoturbidimetric Assay Method)
54	Rheumatoid Factor Kit (Immunoturbidimetric Method)
55	Total Bile Acids Kit (Enzymatic Cycling Assay)
56	Bilirubin Total Kit (DSA Method)
57	Bilirubin Total Kit (VOX Method)
58	Total Cholesterol Kit (CHOD-POD Method)
59	Triglycerides Kit (GPO-POD Method)
60	Total Protein Kit (Biuret Method)
61	Total Protein in Urine/CSF(TPUC)Kit (Pyrogallol Red-Molybdate Method)

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62	Transferrin Kit (Immunoturbidimetric Assay Method)
63	Uric Acid Kit (Uricase-Peroxidase Method)
64	Unsaturated Iron Binding Capacity Kit (Colorimetric Method)
65	Urea Kit (Urease-GLDH, UV Method)
66	Multi Sera Calibrator
67	Specific Proteins Calibrator
68	Prealbumin Calibrator
69	Lipids Calibrator
70	CK-MB Calibrator
71	MYO Calibrator
72	RBP Calibrator
73	UIBC Calibrator
74	IgE Calibrator
75	FER Calibrator
76	ACE Calibrator
77	MALB Calibrator
78	TRF Calibrator
79	β -HB Calibrator
80	HbA1c Calibrator
81	ADA Calibrator
82	C-reactive Protein Calibrator
83	Cystatin C Calibrator
84	β 2-Microglobulin Calibrator(for Serum)
85	β 2-Microglobulin Calibrator(for Urine)
86	Lipoprotein (a) Control
87	HbA1C Control P
88	HbA1C Control N
89	FUN Control P
90	D-Dimer Control
91	Multimmun Control
92	RBP Control
93	UIBC Control
94	G6PD Control
95	ACE Control
96	MALB Control
97	TRF Control
98	β -HB Control
99	TBA Control
100	ADA Control
101	AFU Control
102	ClinChem Multi Control(level 1)
103	ClinChem Multi Control(level 2)

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104	ASO/CRP/RF Triple Control
105	Cystatin C Control
106	β 2-Microglobulin Control
107	TPUC Control
108	HCY Control

Consumables for Chemiluminescence Immunoassay Analyzer:

No.	Product name
1	Reaction Cuvette for Chemiluminescence Immunoassay Analyzer
2	Substrate Solution
3	Wash Buffer
4	DETERGENT C
5	Waste Bin for Chemiluminescence Immunoassay Analyzer
6	Sample Diluent
7	System Wash Solution
8	System Detection Solution

Reagents, Calibrators, and Controls for Chemiluminescence Immunoassay Analyzer:

No.	Product name
1	Free Triiodothyronine (CLIA)
2	Free Thyroxine (CLIA)
3	Total Triiodothyronine (CLIA)
4	Total Thyroxine (CLIA)
5	Thyroid-Stimulating Hormone (CLIA)
6	Thyroglobulin (CLIA)
7	Antibody to thyroglobulin (CLIA)
8	Antibody to thyroid peroxidase (CLIA)
9	Cancer Antigen 125 (CLIA)
10	Carbohydrate Antigen 19-9 (CLIA)
11	Carcinoembryonic Antigen (CLIA)
12	Alpha-fetoprotein (CLIA)
13	Ferritin (CLIA)
14	Cancer Antigen 15-3 (CLIA)
15	Cancer Antigen 72-4 (CLIA)
16	Neuron-specific enolase (CLIA)
17	CYFRA 21-1 (CLIA)
18	Total β Human Chorionic Gonadotropin (CLIA)
19	Luteinizing Hormone (CLIA)
20	Follicle Stimulating Hormone (CLIA)
21	Prolactin (CLIA)

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22	Estriol(CLIA)
23	Progesterone(CLIA)
24	Testosterone(CLIA)
25	Estradiol(CLIA)
26	Dehydroepiandrosterone sulfate(CLIA)
27	Cortisol(CLIA)
28	Adrenocorticotrophic hormone(CLIA)
29	Insulin(CLIA)
30	C-peptide(CLIA)
31	Troponin I(CLIA)
32	Myoglobin(CLIA)
33	Creatine kinase MB(CLIA)
34	B-type natriuretic peptide(CLIA)
35	Antibody to Treponema Pallidum (CLIA)
36	25-OH-Vitamin D Total (CLIA)
37	Vitamin B12(CLIA)
38	Folate(CLIA)
39	Parathyroid hormone(CLIA)
40	Calcitonin(CLIA)
41	Reverse Triiodothyronine(CLIA)
42	Pepsinogen I (CLIA)
43	Pepsinogen II (CLIA)
44	Laminin(CLIA)
45	Hyaluronic Acid(CLIA)
46	N-terminal Peptide of Procollagen Type III(CLIA)
47	Collagen Type IV(CLIA)
48	Procalcitonin (CLIA)
49	Carbohydrate Antigen 50 (CLIA)
50	Carbohydrate Antigen 242(CLIA)
51	Human Epididymal Protein 4 (CLIA)
52	Squamous Cell Carcinoma Antigen (CLIA)
53	ProGRP (CLIA)
54	Total β Human Chorionic Gonadotropin (CLIA)
55	Anti-Mullerian Hormone(CLIA)
56	Red Blood Cell Folate Releasing Reagent
57	Procalcitonin(CLIA)
58	Aldosterone (CLIA)
59	Severe Acute Respiratory Syndrome Coronavirus 2 IgM (CLIA)
60	Severe Acute Respiratory Syndrome Coronavirus 2 IgG (CLIA)
61	Severe Acute Respiratory Syndrome Coronavirus 2 S-RBD IgG (CLIA)
62	Free T3 Calibrators
63	Free T4 Calibrators

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64	Total T3 Calibrators
65	Total T4 Calibrators
66	TSH Calibrators
67	Thyroglobulin Calibrators
68	Anti-Tg Calibrators
69	Anti-TPO Calibrators
70	CA125 Calibrators
71	CA19-9 Calibrators
72	CEA Calibrators
73	AFP Calibrators
74	Ferritin Calibrators
75	CA15-3 Calibrators
76	CA72-4 Calibrators
77	NSE Calibrators
78	CYFRA 21-1 Calibrators
79	Total β HCG Calibrators
80	LH Calibrators
81	FSH Calibrators
82	Prolactin Calibrators
83	Estriol Calibrators
84	Progesterone Calibrators
85	Testosterone Calibrators
86	Estradiol Calibrators
87	DHEA-S Calibrators
88	Cortisol Calibrators
89	ACTH Calibrators
90	Insulin Calibrators
91	C-Peptide Calibrators
92	Troponin I Calibrators
93	MYO Calibrators
94	CK-MB Calibrators
95	BNP Calibrators
96	Anti-TP Calibrators
97	PTH Calibrators
98	Calcitonin Calibrators
99	25-OH-Vitamin D Total Calibrators
100	Vitamin B12 Calibrators
101	Folate Calibrators
102	rT3 Calibrators
103	PG I Calibrators
104	PG II Calibrators
105	CA 50 Calibrators

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106	CA 242 Calibrators
107	HE-4 Calibrators
108	SCCA Calibrators
109	ProGRP Calibrators
110	PCT Calibrators
111	ALD Calibrators
112	Renin Calibrators
113	Thyroid Function Multi Control
114	Anti-thyroid Antibodies Control
115	Tumor Marker Multi Control
116	NSE Control
117	Reproductive Multi Control
118	ACTH Control
119	Immunoassay Multi Control
120	Cardiac Marker Multi Control
121	Anti-TP Positive Control
122	Anti-TP Negative Control
123	Metabolic Multi Control
124	AMH Control
125	rT3 Control
126	Gastritis Multi Control
127	Liver Fibrosis Multi Control
128	PCT Control
129	Tumor Marker Multi Control II
130	ProGRP Control
131	Hypertension Multi Control
132	SARS-CoV-2 IgM/IgG Negative Control
133	SARS-CoV-2 IgM Positive Control
134	SARS-CoV-2 IgG Positive Control
135	SARS-CoV-2 S-RBD IgG Antibody Control (L)
136	SARS-CoV-2 S-RBD IgG Antibody Control (H)

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Attachment II

Reagents, Calibrators, and Controls for Chemiluminescence Immunoassay Analyzer:

No.	Product name
1	Total Prostate Specific Antigen (CLIA)
2	Free Prostate Specific Antigen (CLIA)
3	Total PSA Calibrators
4	Free PSA Calibrators
5	Tumor Marker Multi Control

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Attachment III

Reagents, Calibrators, and Controls for Chemiluminescence Immunoassay Analyzer:

No.	Product name
1	Hepatitis B Surface Antigen (CLIA)
2	Antibody to Hepatitis B Surface Antigen (CLIA)
3	Hepatitis B e Antigen (CLIA)
4	Antibody to Hepatitis B e Antigen (CLIA)
5	Antibody to Hepatitis B Core Antigen (CLIA)
6	Antigen and Antibodies to Human Immunodeficiency Virus (CLIA)
7	HBsAg Calibrators
8	Anti-HBs Calibrators
9	HBeAg Calibrators
10	Anti-HBe Calibrators
11	Anti-HBc Calibrators
12	HIV Calibrators
13	HBsAg Positive Control
14	HBsAg Negative Control
15	Anti-HBs Positive Control
16	Anti-HBs Negative Control
17	HBeAg Positive Control
18	HBeAg Negative Control
19	Anti-HBe Positive Control
20	Anti-HBe Negative Control
21	Anti-HBc Positive Control
22	Anti-HBc Negative Control
23	HIV Ag/Ab Positive Control
24	HIV Ag/Ab Negative Control

Declaration of Conformity



We,

HUMAN Gesellschaft für Biochemica und Diagnostica mbH
Max-Planck-Ring 21
65205 Wiesbaden
Germany

hereby confirm that we have installed a quality management system according to the harmonized standards EN ISO 9001:2015 and EN ISO 13485:2016+AC:2016. Our quality management system has been certified for compliance with said standards by the German Notified Body mdc medical device certification GmbH, Kriegerstr. 6, D-70191 Stuttgart, registered under reference number 0483, respectively (certificates registration numbers are D1030000072 and D1030000073).

Compliance with additional requirements of annex IV (directive 98/79 EC) for products classified as either annex II list A or list B has been certified by the German Notified Body mdc (reg. nos.: D1030000076, D1030000075, D1030000048, D1030000049, D1030000062, D1030000063 and D1030000068 respectively).

We further confirm that the IVD products listed in the attachment are designed, manufactured and controlled by us in accordance with the European directive 98/79 EC and that they meet the essential requirements according to annex I of said directive. Applicable conformity assessment procedures according to annex III (denoted others or H in the attached list) or annex IV (denoted II, A or II, B), whatever applicable, of said directive have been completed for these products. We further confirm that for each IVD product an individual conformity declaration has been prepared.

With the **CE** mark on the listed products we declare in our sole responsibility that the products are in conformity with the applicable directive 98/79/EC and harmonized standards.

HUMAN Gesellschaft für Biochemica und Diagnostica mbH

Date: November 01, 2019

Dr. Torsten Borchers
Vice President Quality Assurance and Regulatory Affairs

Human

Gesellschaft für Biochemica
und Diagnostica mbH
Max-Planck-Ring 21
65205 Wiesbaden-Deilkenheim
Germany

Attachment



List of products which passed applicable conformity assessment procedures
(annex III, annex IV of directive 98/79/EC) by date of signing

Cat.-no.	Product name	Class
10010	Magnesium liquicolor	Others
10010150	Magnesium liquicolor	Others
10010300	Magnesium liquicolor	Others
10010600	Magnesium liquicolor	Others
10011	Calcium liquicolor	Others
10011150	Calcium liquicolor	Others
10011300	Calcium liquicolor	Others
10011600	Calcium liquicolor	Others
10012	Bilirubin liquicolor	Others
10017	Cholesterol liquicolor	Others
10018	HDL Cholesterol	Others
10019	Cholesterol liquicolor	Others
10027	Phosphorus liquirapid	Others
10027150	Phosphorus liquirapid	Others
10027300	Phosphorus liquirapid	Others
10027600	Phosphorus liquirapid	Others
10028	Cholesterol liquicolor	Others
10028150	Cholesterol liquicolor	Others
10028300	Cholesterol liquicolor	Others
10028600	Cholesterol liquicolor	Others
10051	Creatinine liquicolor	Others
10052	auto-Creatinine liquicolor	Others
10052150	auto-Creatinine liquicolor	Others
10052300	auto-Creatinine liquicolor	Others
10052600	auto-Creatinine liquicolor	Others
10053	Creatinine (Enzym) liquicolor	Others
10053150	Creatinine (Enzym) liquicolor	Others
10053300	Creatinine (Enzym) liquicolor	Others
10053600	Creatinine (Enzym) liquicolor	Others
10084	HDL Cholesterol liquicolor	Others
10084150	HDL Cholesterol liquicolor	Others
10084300	HDL Cholesterol liquicolor	Others
10084600	HDL Cholesterol liquicolor	Others
10094	LDL Cholesterol liquicolor	Others
10094150	LDL Cholesterol liquicolor	Others
10094600	LDL Cholesterol liquicolor	Others
10104	Urea Standard	Others
10113	Sodium liquicolor	Others
10113150	Sodium liquicolor	Others
10113300	Sodium liquicolor	Others
10113600	Sodium liquicolor	Others
10114	Sodium Standard	Others
10115	Chloride liquicolor	Others
10118	Potassium liquirapid	Others

Cat.-no.	Product name	Class
10120	Potassium liquiUV	Others
10120150	Potassium liquiUV	Others
10120300	Potassium liquiUV	Others
10120600	Potassium liquiUV	Others
10121	Glucose liquicolor	Others
10126	Potassium Standard	Others
10229	Iron liquicolor	Others
10230	Iron liquicolor	Others
10260	Glucose liquicolor	Others
10260150	Glucose liquicolor	Others
10260300	Glucose liquicolor	Others
10260600	Glucose liquicolor	Others
10284	HDL Cholesterol liquicolor	Others
10294	LDL Cholesterol liquicolor	Others
10505	Urea liquicolor	Others
10506	Urea liquicolor R1	Others
10507	Urea liquicolor R2	Others
10521	Urea liquiUV	Others
10521150	Urea liquiUV	Others
10521300	Urea liquiUV	Others
10521600	Urea liquiUV	Others
10560	Albumin liquicolor	Others
10560150	Albumin liquicolor	Others
10560300	Albumin liquicolor	Others
10560600	Albumin liquicolor	Others
10570	Total Protein liquicolor	Others
10570150	Total Protein liquicolor	Others
10570300	Total Protein liquicolor	Others
10570600	Total Protein liquicolor	Others
10590	Urinary Total Protein liquicolor	Others
10590300	Urinary Total Protein liquicolor	Others
10595	Urinary Total Protein Standard	Others
10657, 10658, 10259	Glycohemoglobin HbA _{1c}	Others
10660	Acid Phosphatase Humazym	Others
10660150	Acid Phosphatase	Others
10660600	Acid Phosphatase	Others
10670	TIBC	Others
10690	Uric acid liquicolor	Others
10691	Uric acid liquicolor	Others
10694	Uric acid liquicolor ^{plus}	Others
10694150	Uric acid liquicolor ^{plus}	Others
10694300	Uric acid liquicolor ^{plus}	Others
10694600	Uric acid liquicolor ^{plus}	Others
10720P	Triglycerides liquicolor ^{mono}	Others



Cat.-no.	Product name	Class
10724	Triglycerides liquicolor ^{mono}	Others
10724150	Triglycerides liquicolor ^{mono}	Others
10724300	Triglycerides liquicolor ^{mono}	Others
10724600	Triglycerides liquicolor ^{mono}	Others
10725	Triglycerides liquicolor ^{mono}	Others
10740	Bilirubin D&T liquicolor	Others
10741	auto-Bilirubin-D liquicolor	Others
10741150	auto-Bilirubin-D liquicolor	Others
10741300	auto-Bilirubin-D liquicolor	Others
10741600	auto-Bilirubin-D liquicolor	Others
10742	auto-Bilirubin-T liquicolor	Others
10742150	auto-Bilirubin-T liquicolor	Others
10742300	auto-Bilirubin-T liquicolor	Others
10742600	auto-Bilirubin-T liquicolor	Others
10751	Hemoglobin liquicolor	Others
10770	HbA1c liquidirect	Others
10770600	HbA1c liquidirect	Others
10775	HbA1c liquidirect, Control Set	Others
10776	HbA1c liquidirect, Calibrator Set	Others
10786	Glucose liquiUV Mono	Others
11101	Apo A1	Others
11101600	Apolipoprotein A1 (APO A1)	Others
11102	Apo B	Others
11102600	Apolipoprotein B (APO B)	Others
11104	Apo A1/B Standard	Others
11105	Lp(a)	Others
11105600	Lp(a)	Others
11107	Lp(a) Standard	Others
11110	Complement C3	Others
11110600	Complement C3	Others
11113	Complement C4	Others
11113600	Complement C4	Others
11115	Transferrin	Others
11115600	Transferrin	Others
11117	C3/C4/TRF Standard	Others
11120	Microalbumin	Others
11120600	Microalbumin	Others
11124	Microalbumin Standard	Others
11140	Homocysteine liquiUV	Others
11140600	Homocysteine liquiUV	Others
11141	CRP Buffer	Others
11143	Homocysteine liquiUV Control Set	Others
11145	Homocysteine liquiUV Calibrator Set	Others
11150	Cystatin-C liquidirect	Others
11150600	Cystatin-C liquidirect	Others
11153	Cystatin-C liquidirect Controls	Others
11155	Cystatin-C liquidirectCalibrators	Others
11241	CRP	Others
11241600	C-Reactive Protein (CRP)	Others
11251300	Anti-Streptolysin-O	Others
11251600	Anti-Streptolysin-O	Others
11251P	ASO Reagent Kit	Others
11261P	RF Reagent Kit	Others
11261300	Rheumatoid Factors	Others

Cat.-no.	Product name	Class
11261600	Rheumatoid Factors	Others
11261PA	RF Reagent Kit	Others
11341	CRP Standard	Others
11351	ASO Standard	Others
11361	RF Standard	Others
11501	Immunglobulins direct IgA direct Reagent kit	Others
11501600	Immunoglobulin A direct	Others
11502	Immunglobulins direct IgG direct Reagent kit	Others
11502600	Immunoglobulin G direct	Others
11503	Immunglobulins direct IgM direct Reagent kit	Others
11503600	Immunoglobulin M direct	Others
11504	Immunglobulins direct IgG ,IgA, IgM Calibrator Set	Others
11505	Immunglobulins direct Buffer	Others
11610	Ferritin Reagent Kit	Others
11610600	Ferritin	Others
11614	Ferritin Calibrator	Others
12005	CK NAC M-Test	Others
12006	Lipase liquicolor	Others
12006600	Lipase liquicolor	Others
12007	Cholinesterase liquicolor	Others
12007300	Cholinesterase liquicolor	Others
12008	CK-MB NAC M-Test	Others
12009	Pancreas Amylase liquicolor	Others
12009600	Pancreas-Amylase liquicolor	Others
12011	GOT(ASAT) liquiUV	Others
12012	GPT(ALAT) liquiUV	Others
12013	gamma-GT liquicolor	Others
12014	LDH SCE mod. liquiUV	Others
12014150	LDH SCE mod. liquiUV	Others
12014300	LDH SCE mod. liquiUV	Others
12014600	LDH SCE mod. liquiUV	Others
12015	CK NAC liquiUV	Others
12015150	CK NAC liquiUV	Others
12015600	CK-NAC liquiUV	Others
12017	Alk.Phosphatase liquicolor	Others
12018	Alpha-Amylase liquicolor	Others
12021	GOT (ASAT) IFCC mod. liquiUV	Others
12021150	GOT (ASAT) IFCC mod. liquiUV	Others
12021300	GOT (ASAT) IFCC mod. liquiUV	Others
12021600	GOT (ASAT) IFCC mod. liquiUV	Others
12022	GPT(ALAT) IFCC mod. liquiUV	Others
12022150	GPT(ALAT) IFCC mod. liquiUV	Others
12022300	GPT(ALAT) IFCC mod. liquiUV	Others
12022600	GPT(ALAT) IFCC mod. liquiUV	Others
12023	gamma GT liquicolor	Others
12023150	gamma GT liquicolor	Others
12023300	gamma GT liquicolor	Others
12023600	gamma GT liquicolor	Others



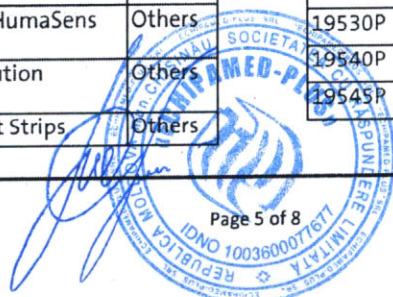
Cat.-no.	Product name	Class
12024	LDH liquiUV	Others
12026	Lipase liquicolor	Others
12027	Alkaline Phosphatase liquicolor	Others
12027150	Alkaline Phosphatase liquicolor	Others
12027300	Alkaline Phosphatase opt. liquicolor	Others
12027600	Alkaline Phosphatase opt. liquicolor	Others
12028	alpha-Amylase liquicolor	Others
12028150	alpha-Amylase liquicolor	Others
12028300	alpha-Amylase liquicolor	Others
12028600	alpha-Amylase liquicolor	Others
12029	Pancreas Amylase liquicolor	Others
12031	GOT(ASAT) liquiUV	Others
12032	GPT(ALT) liquiUV	Others
12033	Gamma-GT liquicolor	Others
12037	Alkaline Phosphatase liquicolor	Others
12117	Alkaline Phosphatase liquicolor IFCC	Others
12117300	Alkaline Phosphatase liquicolor IFCC	Others
12117600	Alkaline Phosphatase liquicolor IFCC	Others
12118	CK MB liquiUV	Others
12118150	CK MB liquiUV	Others
12118600	CK-MB liquiUV	Others
12211	GOT(ASAT) liquiUV M-Test	Others
12212	GPT(ALT) liquiUV M-Test	Others
12213	Gamma-GT liquicolor M-Test	Others
12214	LDH liquiUV M-Test	Others
12217	Alk.Phos.liquicolor M-Test	Others
12218	Alpha-Amylase liquicolor M-Test	Others
12290	Iron TPTZ liquicolor	Others
12290150	Iron TPTZ liquicolor	Others
12290300	Iron TPTZ liquicolor	Others
12290600	Iron TPTZ liquicolor	Others
12291	Iron TPTZ liquicolor	Others
12660	Acid Phosphatase Humazym	Others
13010	TURBIDOS	Others
13020600	Ferritin Calibrator 500	Others
13151	Serodos Plus	Others
13160	Autocal	Others
13511	Humatrol N	Others
13512	Humatrol P	Others
13611	CK-MB Control	Others
13612	CK-MB Calibrator	Others
13951	Serodos	Others
15024	HumaSRate	Others
15024/40	HSRate Control	Others
15500	HumaxHCT (220V)	Others
15500/110	HumaxHCT (110V)	Others
15501	Haematocrit rotor	Others
156004	Albumin liquicolor	Others

Cat.-no.	Product name	Class
157004	Total Protein liquicolor	Others
15650	HumaClot Duo ^{plus}	Others
15660	HumaClot Quattro	Others
15800	HumaClot Pro	Others
15800/20	HumaClot Pro – Wash Solution	Others
15800/30	HumaClot Pro – Cleaner	Others
15910	HumaCLIA 150	Others
16001/03	Micro Cuvettes Hb	Others
16070	HumaMeter Hb ^{plus}	Others
16070/1	Reagent Hb	Others
16070/25		
16070/2	Calibrator Set Hb	Others
16070/3	Control Set Hb	Others
16080	HumaMeter A1c	Others
16085/50	HumaMeter A1c Reagent Kit	Others
16086	HumaMeter A1c Control Kit	Others
16180	HumaNex A1c	Others
16185	HumaNex A1c Reagent Kit	Others
16300	ELISYS QUATTRO	Others
16350/10	HC5-Basolyse	Others
16350/20	HC5-Eolyse	Others
16350/40	HC5-Control	Others
16420/30	HumaCount 30 ^{TS}	Others
16420/80	HumaCount 80 ^{TS}	Others
16430	HumaCount 5L	Others
16430/10	Automatic Sample Loader	Others
16430/20	HC5L-Diluent	Others
16430/30	HC5L-Lyse	Others
16430/40	HC5L-Diff	Others
16430/50	HC5L-Control	Others
16450	HumaCount 5D	Others
16450/10	HC5D Diluent	Others
16450/20	HC5D CBC Lyse	Others
16450/30	HC5D Diff Lyse	Others
16450/40	HC5D Control	Others
16450/60	HC5D Clean	Others
16670	Humareader HS	Others
16660	HumaStar 600	Others
16660/11	ISE Cleaner	Others
16660/12	ISE Conditioner	Others
16660/13	ISE Urine Diluent	Others
16660/14	ISE Standard Pack	Others
16661/01	Chimney	Others
16663/10	Diluent	Others
16663/11	Diluent-2	Others
16663/20	Cuvette Clean	Others
16663/25	Tip Cleaning Kit	Others
16700	Humalyzer 3000	Others
16800	Humalyzer 3500	Others
16880	HumaStar 80	Others



Cat.-no.	Product name	Class
16890	HumaStar 100	Others
16895	HumaStar 200	Others
16930	HumaStar 300SR	Others
16923/20	Cuvette Clean	Others
17200	ELISYS DUO	Others
17350	ELISYS UNO	Others
17400/10	HC-Diluent	Others
17400/11	HC-Diluent	Others
17400/20	HC-Lyse CF	Others
17400/22	HC-Lyse CF	Others
17400/30	HC-Cleaner	Others
17400/31	HC-Cleaner	Others
17400/40	HC-Control	Others
17400/50	HC-Calibrator	Others
17470/10	HumaLyte Plus ³	Others
17470/20	HumaLyte Plus ⁵	Others
17470/11	K Electrode	Others
17470/12	Na Electrode	Others
17470/13	Cl Electrode	Others
17470/14	Ca Electrode	Others
17470/15	pH Electrode	Others
17470/17	Reference Electrode	Others
17470/70	QC Solution	Others
17470/71	Daily Cleaning Solution	Others
17470/72	Weekly Cleaning Solution	Others
17470/74	K Filling Solution	Others
17470/75	pH / Na / Cl Filling Solution	Others
17470/76	Ca Filling Solution	Others
17470/78	Reference Filling Solution	Others
17470/79	Na Conditioner	Others
17470/82	Reagent Pack HumaLyte Plus ³	Others
17470/83	Reagent Pack HumaLyte Plus ⁵	Others
17470/86	Urine Diluent	Others
17470/110	QC Solution	Others
17546	HumaSens ^{plus} Uric Acid Test Strips	Others
17546/10	HumaSens ^{plus} Uric Acid Control Solution normal	Others
17547	HumaSens ^{plus} Total Cholesterol Test Strips	Others
17547/10	HumaSens ^{plus} Total Cholesterol Control Solution normal	Others
17560	HumaSens 2.0 Starter Pack	II,B
17561	HumaSens 2.0 ^{plus} Starter Pack	Others
17562	Glucose Test Strips Blue HumaSens2.0/ HumaSens2.0 ^{plus} / HumaSens/HumaSens ^{plus}	II,B
17562/2	Glucose Test Strips Blue HumaSens2.0/ HumaSens2.0 ^{plus} / HumaSens/HumaSens ^{plus}	II,B
17562/10	Glucose Control HumaSens* / HumaSens ^{plus} * / HumaSens 2.0 / HumaSens2.0 ^{plus} (*BLUE GLU strip)	II/B
17566	Uric Acid Test Strips HumaSens 2.0 ^{plus}	Others
17566/10	Uric Acid Control Solution HumaSens 2.0 ^{plus}	Others
17567	Total Cholesterol Test Strips	Others

Cat.-no.	Product name	Class
	HumaSens 2.0 ^{plus}	
17567/10	Total Cholesterol Control Solution HumaSens 2.0 ^{plus}	Others
17600	Combilyzer ¹³	Others
18000	HumaReader Single ^{plus}	Others
18200	HumaLyzer Primus	Others
18222	Flow Cell Cleaner	Others
18250	HumaLyzer 4000	Others
18300	HumaLyzer 2000	Others
18460	CombiWash	Others
18680	Humaclot Junior	Others
18971	Wash Additive	Others
18973	Cuvette Clean	Others
18974	Special Wash Solution	Others
18974/2	Special Wash Solution-2	Others
19110L	Humapette Smart Line 0.5 – 10µl	Others
19120L	Humapette Smart Line 5 – 50µl	Others
19125L	Humapette Smart Line 10 – 100µl	Others
19130L	Humapette Smart Line 20 – 200µl	Others
19140L	Humapette Smart Line 100 – 1000µl	Others
19150L	Humapette Smart Line 1000 – 5000µl	Others
19500L	Humapette Smart Line 5µl	Others
19505L	Humapette Smart Line 10µl	Others
19510L	Humapette Smart Line 20µl	Others
19515L	Humapette Smart Line 25µl	Others
19520L	Humapette Smart Line 50µl	Others
19525L	Humapette Smart Line 100µl	Others
19530L	Humapette Smart Line 200µl	Others
19535L	Humapette Smart Line 250µl	Others
19540L	Humapette Smart Line 500µl	Others
19545L	Humapette Smart Line 1000µl	Others
19110P	HumaPette Digital 0.5-10µl	Others
19120P	HumaPette Digital 2-20µl	Others
19125P	HumaPette Digital 10-100µl	Others
19130P	HumaPette Digital 20-200µl	Others
19140P	HumaPette Digital 100-1000µl	Others
19150P	HumaPette Digital 0.5-5.0ml	Others
19160P	HumaPette Digital 1.0-10.0ml	Others
19320P	HumaPette Transfer-8 5-50µl	Others
19330P	HumaPette Transfer-8 30-300µl	Others
19505P	HumaPette Typ Fix 10µl	Others
19510P	HumaPette Typ Fix 20µl	Others
19515P	HumaPette Typ Fix 25µl	Others
19520P	HumaPette Typ Fix 50µl	Others
19525P	HumaPette Typ Fix 100µl	Others
19530P	HumaPette Typ Fix 200µl	Others
19540P	HumaPette Typ Fix 500µl	Others
19545P	HumaPette Typ Fix 1000µl	Others



Cat.-no.	Product name	Class
54025	ft4 ELISA	Others
54030	TSH ELISA	Others
55010	Testosterone ELISA	Others
55020	Progesterone ELISA	Others
55030	Estradiol ELISA	Others
55040	Estriol ELISA	Others
55050	Cortisol ELISA	Others
55060	DHEA-S ELISA	Others
55500	25-OH Vitamin D	Others
57002P, 57004P	Hexagon HIV	II, A
573351	Sodium rapid	Others
58002	Hexagon Chagas	Others
58012	Hexagon Chlamydia	II, B
58022	Hexagon H.Pylori	Others
58032	HEXAGON TB	Others
58042	Hexagon Syphilis	Others
58054	Hexagon Malaria	Others
58062	HEXAGON Strep A	Others
58082	HEXAGON Dengue	Others
58912	Hexagon Chlamydia Collect	II, B
60022	Fertitex Mono	Others
68004	HumaPreg ^{Urine}	Others
68902, 68932	Hexagon hCG 1-Step ^{Urine}	Others
71012	HumaType Anti-A	II, A
71022	HumaType Anti-B	II, A
71032	HumaType Anti-A,B	II, A
71042	HumaType Anti-D IgM	II, A
71052	HumaType Anti-D IgM/IgG	II, A
71062	HumaType Anti-Human Globulin	II, B
71072	HumaType Albumin 22%	Others
73005/12	HumaTube No Additive (Z)	Others
73020/12	HumaTube Serum C/A (Z)	Others
73023/12	HumaTube Serum C/A (Z)	Others
73030/12	HumaTube Serum Gel-C/A (Z)	Others
73032/12	HumaTube K2-EDTA (K2E)	Others
73040/12	HumaTube K3-EDTA (K3E)	Others
73045/12	HumaTube K3-EDTA (K3E)	Others
73050/12	HumaTube Li-Heparin (LH)	Others
73060/12	HumaTube Na-Citrate 3.2 % (9NC)	Others
73070/12	HumaTube Glucose (FH)	Others
961000	HumaLoop T	Others
962000	HumaLoop M	Others
963100	HumaTurb A	Others
963200	HumaTurb C + A	Others
964000	HumaHeat	Others
ITC02850	HumaScan	Others
ITC30500	IMTEC-Gliadin-Antibodies IgG	Others
ITC30505	IMTEC-d-Gliadin-Antibodies IgG	Others
ITC30600	IMTEC-Gliadin-Antibodies IgA	Others
ITC30605	IMTEC-d-Gliadin-Antibodies IgA	Others

Cat.-no.	Product name	Class
ITC30701	IMTEC-Gastro-LIA	Others
ITC40040	IMTEC-Salmononella-Antibodies Screen (cut-off)	Others
ITC40050	IMTEC-Salmononella-Antibodies IgA (cut-off)	Others
ITC59001	IMTEC-DsDNA-Antibodies	Others
ITC59002	IMTEC-Nucleosome-Antibodies	Others
ITC59005	IMTEC-ssDNA-Antibodies	Others
ITC59011	IMTEC-Phosphatidylserine-Antibodies IgG	Others
ITC59021	IMTEC-Phosphatidylserine-Antibodies IgM	Others
ITC59022	IMTEC-Phosphatidylserine-Antibodies Combi	Others
ITC59027	IMTEC-Phosphatidylserine-Antibodies Screen	Others
ITC59030	IMTEC-CIC Screen (cut-off)	Others
ITC59031	IMTEC-CIC IgG	Others
ITC59032	IMTEC-C3d-CIC	Others
ITC59033	IMTEC-Anti-C1q-Antibodies	Others
ITC59035	IMTEC-Complement Activity	Others
ITC59050	IMTEC-beta2-Glycoprotein 1-Antibodies Screen	Others
ITC59070	IMTEC-Phospholipid-Antibodies Screen	Others
ITC59071	IMTEC-Cardiolipin-Antibodies IgG	Others
ITC59076	IMTEC-Cardiolipin-Antibodies Screen	Others
ITC59081	IMTEC-Cardiolipin-Antibodies IgM	Others
ITC59082	IMTEC-Cardiolipin-Antibodies Combi	Others
ITC59150	IMTEC-beta2-Glycoprotein 1-Antibodies IgG	Others
ITC59250	IMTEC-beta2-Glycoprotein 1-Antibodies IgM	Others
ITC59400	IMTEC-Phosphatidylethanolamine-Antibodies Screen	Others
ITC59450	IMTEC-Prothrombin-Antibodies Screen	Others
ITC59500	IMTEC-oxLDL-Antibodies Ig(GM)	Others
ITC59550	IMTEC-Annexin V-Antibodies Screen	Others
ITC60000	IMTEC-RF Screen	Others
ITC60001	IMTEC-ANA Screen	Others
ITC60003	IMTEC-RF IgM	Others
ITC60005	IMTEC-ENA Screen	Others
ITC60007	IMTEC-RF IgG	Others
ITC60010	IMTEC-RF IgA	Others
ITC60015	IMTEC-RA33-Antibodies	Others
ITC60021	IMTEC-CCP-Antibodies	Others
ITC60029	IMTEC-SmD1-Antibodies IgG	Others
ITC60031	IMTEC-Histone-Antibodies	Others
ITC60033	IMTEC-ENA Profile	Others
ITC60040	IMTEC-AMA M2	Others
ITC60200	IMTEC-Myositis LIA	Others
ITC60201	IMTEC-Myositis LIA PL	Others
ITC66005	IMTEC-Liver Screen S	Others
ITC66040	IMTEC-Sp100-Antibodies	Others
ITC66050	IMTEC-LKM1-Antibodies	Others



Cat.-no.	Product name	Class
ITC66060	IMTEC-SLA Antikörper (cut-off)	Others
ITC66205	IMTEC-Liver-LIA S	Others
ITC70001	IMTEC-ANA Screen (cut-off)	Others
ITC70005	IMTEC-ENA Screen (cut-off)	Others
ITC70022	IMTEC-U1-snRNP-Antibodies	Others
ITC70024	IMTEC-SS-B/La-Antibodies	Others
ITC70025	IMTEC-Jo1-Antibodies	Others
ITC70026	IMTEC-SS-A/Ro-Antibodies	Others
ITC70028	IMTEC-Scl70-Antibodies	Others
ITC80000	HumaBlot 44 ^{FA}	Others
ITC82020	IMTEC-PR3-ANCA	Others
ITC82030	IMTEC-MPO-ANCA	Others
ITC82040	IMTEC-Vasculitis-LIA	Others

Cat.-no.	Product name	Class
ITC82070	IMTEC-GBM-Antibodies	Others
ITC85010	IMTEC-TG-Antibodies	Others
ITC85020	IMTEC-TPO-Antibodies	Others
ITC85030	IMTEC-TSH Receptor-Antibodies	Others
ITC92000	IMTEC-ANA-LIA	Others
ITC92000-1	IMTEC-ANA-LIA	Others
ITC92000-2	IMTEC-ANA-LIA	Others
ITC92000-3	IMTEC-ANA-LIA	Others
ITC92000-4	IMTEC-ANA-LIA	Others
ITC92000-5	IMTEC-ANA-LIA	Others
ITC92005	IMTEC-ANA-LIA Maxx	Others

Class: acc. to directive 98/79 EC

II, A = test listed in annex II, list A

II, B = test listed in annex II, list B

H = test for home use, not listed in annex II

Others





Product Service

Certificate

No. Q5 026709 0009 Rev. 01

Holder of Certificate: DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
 IZ-NOE Sued
 Hondastrasse, Objekt M55
 2351 Wr. Neudorf
 AUSTRIA

Certification Mark:



Scope of Certificate: Design, development, production and distribution of in-vitro diagnostic reagents and testkits in the areas of immunological detection of infectious diseases, immunochemistry/immunology/clinical chemistry biomarkers (analytes: enzymes, substrates, electrolytes reagents; controls/standards/calibrators), urinalysis, haematology, haemostasis and immuno haematology (blood grouping). Distribution of in-vitro diagnostic instruments including accessories for immunology, clinical chemistry, haematology, haemostasis and urinalysis.

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 026709 0009 Rev. 01

Report No.: 713237224
Valid from: 2022-03-29
Valid until: 2025-03-28



C. Dicks

Date, 2022-03-17

Christoph Dicks
 Head of Certification/Notified Body



Certificate

No. Q5 026709 0009 Rev. 01

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): DIALAB Produktion und Vertrieb von chemisch-technischen
 Produkten und Laborinstrumenten Gesellschaft m.b.H.
 IZ-NOE Sued, Hondastrasse, Objekt M55, 2351 Wr. Neudorf,
 AUSTRIA

See Scope of Certificate

Parameters: ./.



EC DECLARATION OF CONFORMITY
EG-KONFORMITÄTSERKLÄRUNG



Dialab Produktion und Vertrieb von
chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55, A-2351 Wiener Neudorf

REF	Product Name / Produktname	Content / Inhalt
	See addendum to the declaration of Conformity	

We declare, on our own responsibility, that our above-mentioned product classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC:

Devices other than those covered by Annex II

meets the applicable provisions of the EU Directive 98/79/EC for in-vitro-diagnostic medical devices and the Austrian Medical Product Law.

This Declaration is based on the Conformity Assessment Procedure according to Annex III of the aforesaid Directive .

Hiermit erklären wir, auf eigene Verantwortung, dass unser oben genanntes Produkt, gemäß der Richtlinie 98/79/EG über In-vitro-Diagnostika klassifiziert als:

Andere als die in Anhang II genannten Produkte

die anwendbaren Vorschriften der EU-Richtlinie 98/79/EG über in-Vitro-Diagnostika und des Österreichischen Medizinproduktegesetzes erfüllt.

Diese Erklärung basiert auf dem Konformitätsbewertungsverfahren nach Anhang III der oben angeführten Richtlinie

Wiener Neudorf, 2023-10-04


Almira Dugic
Qualitätsmanagementbeauftragte
Quality Management Representative

**Addendum to the Declaration of Conformity of Devices
other than those covered by Annex II**

CLINICAL CHEMISTRY

Reagents REF	Product	Content
913816	Adenosine Deaminase (ADA), Enzymatic	6 x 25 mL
913813	Adenosine Deaminase (ADA), Enzymatic	3 x 25 mL
917810	Adenosine Deaminase (ADA), Enzymatic	3 x 10 mL
D97202B	Albumin, BCG	1 x 1 L
D09550	Albumin, BCG	4 x 250 mL
D97203	Albumin, BCG	5 x 100 mL
D00204	Albumin, BCG	5 x 50 mL
D00205	Albumin, BCG	5 x 25 mL
D00206	Albumin, BCG	5 x 10 mL
D51911	Albumin, BCG	10 x 50 mL
D0401917	Albumin, BCG	9 x 65 mL
DK0701	Albumin, BCG	5 x 50 mL
DA0801	Albumin, BCG	5 x 50 mL
DT1001	Albumin, BCG	4 x 50 mL
DE1801	Albumin, BCG	10 x 50 mL
DB20301	Albumin, BCG	10 x 50 mL
D03101B	Alkaline Phosphatase, IFCC	1 x 1.25 L (1 x 1 L R1 + 1 x 0.25 L R2)
D95564	Alkaline Phosphatase, IFCC	5 x 100 mL (4 x 100 mL R1 + 1 x 100 mL R2)
D95565	Alkaline Phosphatase, IFCC	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
D00523	Alkaline Phosphatase, IFCC	5 x 25 mL (4 x 25 mL R1 + 1 x 25 mL R2)
D00524	Alkaline Phosphatase, IFCC	5 x 10 mL (4 x 10 mL R1 + 1 x 10 mL R2)
D52911	Alkaline Phosphatase, IFCC	10 x 50 mL (10 x 40 mL R1 + 4 x 25 mL R2)
D0402917	Alkaline Phosphatase, IFCC	5 x 62.5 mL (4 x 62.5 mL R1 + 1 x 62.5 mL R2)
DA0803	Alkaline Phosphatase, IFCC	5 x 50 mL (5 x 40 mL R1 + 5 x 10 mL R2)
DT1003	Alkaline Phosphatase, IFCC	4 x 62.5 mL (4 x 50 mL R1 + 4 x 12.5 mL R2)
DK0703	Alkaline Phosphatase, IFCC	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
DE1803	Alkaline Phosphatase, IFCC	2 x 62.5 mL (2 x 50 mL R1 + 2 x 12.5 mL R2)
DB20302	Alkaline Phosphatase, IFCC	4 x 62.5 mL (4 x 50 mL R1 + 4 x 12.5 mL R2)
D03103B	Alpha-Amylase, mod. IFCC	1 x 1.25 L (1 x 1 L R1 + 1 x 250 mL R2)
D94570	Alpha-Amylase, mod. IFCC	5 x 100 mL (4 x 100 mL R1 + 1 x 100 mL R2)
D94571	Alpha-Amylase, mod. IFCC	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
D00578	Alpha-Amylase, mod. IFCC	5 x 25 mL (4 x 25 mL R1 + 1 x 25 mL R2)
D96569	Alpha-Amylase, mod. IFCC	5 x 10 mL (4 x 10 mL R1 + 1 x 10 mL R2)
D54911	Alpha-Amylase, mod. IFCC	5 x 50 mL (4 x 50 mL R1 + 2 x 25 mL R2)
D0406917	Alpha-Amylase, mod. IFCC	5 x 62.5 mL (4 x 62.5 mL R1 + 1 x 62.5 mL R2)
DK0705	Alpha-Amylase, mod. IFCC	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
DA0806	Alpha-Amylase, mod. IFCC	5 x 20 mL (4 x 20 mL R1 + 1 x 20 mL R2)
DT1006	Alpha-Amylase, mod. IFCC	5 x 20 mL (4 x 20 mL R1 + 1 x 20 mL R2)
DE1806	Alpha-Amylase, mod. IFCC	2 x 62.5 mL (2 x 50 mL R1 + 2 x 12.5 mL R2)
DB20304	Alpha-Amylase, mod. IFCC	4 x 62.5 mL (4 x 50 mL R1 + 4 x 12.5 mL R2)
397756B	alpha-Amylase, CNP-G3	1 x 1 L
397758	alpha-Amylase, CNP-G3	5 x 100 mL
397759	alpha-Amylase, CNP-G3	5 x 50 mL
300760	alpha-Amylase, CNP-G3	5 x 25 mL
396754	alpha-Amylase, CNP-G3	5 x 10 mL
355911	alpha-Amylase, CNP-G3	10 x 50 mL

D00591	CK-NAC, opt. DGKC / IFCC	5 x 100 mL (4 x 100 mL R1 + 1 x 100 mL R2)
D94581	CK-NAC, opt. DGKC / IFCC	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
D00592	CK-NAC, opt. DGKC / IFCC	5 x 25 mL (4 x 25 mL R1 + 1 x 25 mL R2)
D98579	CK-NAC, opt. DGKC / IFCC	5 x 10 mL (4 x 10 mL R1 + 1 x 10 mL R2)
D64911	CK-NAC, opt. DGKC / IFCC	5 x 50 mL (4 x 50 mL R1 + 2 x 25 mL R2)
D0421917	CK-NAC, opt. DGKC / IFCC	5 x 62.5 mL (4 x 62.5 mL R1 + 1 x 62.5 mL R2)
DA0819	CK-NAC, opt. DGKC / IFCC	5 x 50 mL (5 x 40 mL R1 + 5 x 10 mL R2)
DT1019	CK-NAC, opt. DGKC / IFCC	4 x 62.5 mL (4 x 50 mL R1 + 4 x 12.5 mL R2)
DK0719	CK-NAC, opt. DGKC / IFCC	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
DE1819	CK-NAC, opt. DGKC / IFCC	2 x 62.5 mL (2 x 50 mL R1 + 2 x 12.5 mL R2)
DB20315	CK-NAC, opt. DGKC / IFCC	4 x 62.5 mL (4 x 50 mL R1 + 4 x 12.5 mL R2)
507101B	Copper, 3,5-DiBr-PAESA	1 x 1 L
507140	Copper, 3,5-DiBr-PAESA	5 x 25 mL
545911	Copper, 3,5-DiBr-PAESA	5 x 50 mL
50447917	Copper, 3,5-DiBr-PAESA	5 x 50 mL
5A0821	Copper, 3,5-DiBr-PAESA	5 x 20 mL
5T1021	Copper, 3,5-DiBr-PAESA	5 x 20 mL
5K0720	Copper, 3,5-DiBr-PAESA	5 x 50 mL
5E1821	Copper, 3,5-DiBr-PAESA	5 x 20 mL
5T1221	Copper, 3,5-DiBr-PAESA	4 x 50 mL
D11112B	Creatinine, Enzymatic, PAP	1 x 1 L (1 x 0.75 L R1 + 1 x 0.25 L R2)
D06420	Creatinine, Enzymatic, PAP	4 x 100 mL (4 x 75 mL R1 + 1 x 100 mL R2)
D06430	Creatinine, Enzymatic, PAP	4 x 50 mL (4 x 37.5 mL R1 + 1 x 50 mL R2)
D06440	Creatinine, Enzymatic, PAP	4 x 25 mL (4 x 18.75 mL R1 + 1 x 25 mL R2)
D06450	Creatinine, Enzymatic, PAP	4 x 10 mL (4 x 7.5 mL R1 + 1 x 10 mL R2)
D69911	Creatinine, Enzymatic, PAP	4 x 50 mL (3 x 50 mL R1 + 2 x 25 mL R2)
D0411917	Creatinine, Enzymatic, PAP	4 x 50 mL (3 x 50 mL R1 + 1 x 50 mL R2)
DA0822	Creatinine, Enzymatic, PAP	5 x 50 mL (5 x 37.5 mL R1 + 5 x 12.5 mL R2)
DT1022	Creatinine, Enzymatic, PAP	4 x 50 mL (4 x 37.5 mL R1 + 4 x 12.5 mL R2)
DK0721	Creatinine, Enzymatic, PAP	5 x 40 mL (4 x 37.5 mL R1 + 1 x 50 mL R2)
DE1822	Creatinine, Enzymatic, PAP	4 x 50 mL (4 x 37.5 mL R1 + 4 x 12.5 mL R2)
D03111B	Creatinine, mod. Jaffe	1 x 1.25 L (1 x 1 L R1 + 1 x 0.25 L R2)
D95595	Creatinine, mod. Jaffe	5 x 100 mL (4 x 100 mL R1 + 1 x 100 mL R2)
D00616	Creatinine, mod. Jaffe	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
D00617	Creatinine, mod. Jaffe	5 x 25 mL (4 x 25 mL R1 + 1 x 25 mL R2)
D00618	Creatinine, mod. Jaffe	5 x 10 mL (4 x 10 mL R1 + 1 x 10 mL R2)
D66911	Creatinine, mod. Jaffe	10 x 50 mL (10 x 40 mL R1 + 4 x 25 mL R2)
D0422917	Creatinine, mod. Jaffe	5 x 62.5 mL (4 x 62.5 mL R1 + 1 x 62.5 mL R2)
DA0823	Creatinine, mod. Jaffe	5 x 50 mL (5 x 40 mL R1 + 5 x 10 mL R2)
DT1023	Creatinine, mod. Jaffe	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
DK0722	Creatinine, mod. Jaffe	4 x 62.5 mL (4 x 50 mL R1 + 4 x 12.5 mL R2)
DE1823	Creatinine, mod. Jaffe	4 x 62.5 mL (4 x 50 mL R1 + 4 x 12.5 mL R2)
DB20317	Creatinine, mod. Jaffe	4 x 62.5 mL (4 x 50 mL R1 + 4 x 12.5 mL R2)
D07830	Ethanol, Enzymatic, UV	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
D07840	Ethanol, Enzymatic, UV	5 x 25 mL (4 x 25 mL R1 + 1 x 25 mL R2)
D07850	Ethanol, Enzymatic, UV	5 x 10 mL (4 x 10 mL R1 + 1 x 10 mL R2)
D67911	Ethanol, Enzymatic, UV	5 x 50 mL (4 x 50 mL R1 + 2 x 25 mL R2)
D0407917	Ethanol, Enzymatic, UV	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
DA0824	Ethanol, Enzymatic, UV	5 x 20 mL (4 x 20 mL R1 + 1 x 20 mL R2)
DT1024	Ethanol, Enzymatic, UV	5 x 20 mL (4 x 20 mL R1 + 1 x 20 mL R2)
DK0723	Ethanol, Enzymatic, UV	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
DE1824	Ethanol, Enzymatic, UV	2 x 62.5 mL (2 x 50 mL R1 + 2 x 12.5 mL R2)
310110B	Fructosamine, NBT	1 x 1 L (1 x 700 mL + 3 x 100 mL R1a)
310140	Fructosamine, NBT	2 x 20 mL (2 x 14 mL R1 + 2 x 6 mL R1a)

D03121B	Urea UV Auto, Urease / GLDH	1 x 1.25 L (1 x 1 L R1 + 1 x 0.25 L R2)
D95704	Urea UV Auto, Urease / GLDH	5 x 100 mL (4 x 100 mL R1 + 1 x 100 mL R2)
D98707	Urea UV Auto, Urease / GLDH	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
D00715	Urea UV Auto, Urease / GLDH	5 x 25 mL (4 x 25 mL R1 + 1 x 25 mL R2)
D00716	Urea UV Auto, Urease / GLDH	5 x 10 mL (4 x 10 mL R1 + 1 x 10 mL R2)
D82911	Urea UV Auto, Urease / GLDH	10 x 50 mL (10 x 40 mL R1 + 4 x 25 mL R2)
D0439917	Urea UV Auto, Urease / GLDH	5 x 62.5 mL (4 x 62.5 mL R1 + 1 x 62.5 mL R2)
DA0845	Urea UV Auto, Urease / GLDH	5 x 50 mL (5 x 40 mL R1 + 5 x 10 mL R2)
DT1045	Urea UV Auto, Urease / GLDH	4 x 62.5 mL (4 x 50 mL R1 + 4 x 12.5 mL R2)
DK0742	Urea UV Auto, Urease / GLDH	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
DE1845	Urea UV Auto, Urease / GLDH	4 x 62.5 mL (4 x 50 mL R1 + 4 x 12.5 mL R2)
DB20333	Urea UV Auto, Urease / GLDH	4 x 62.5 mL (4 x 50 mL R1 + 4 x 12.5 mL R2)
D10704	Urea UV Auto, Urease / GLDH	5 x 100 mL (4 x 100 mL R1 + 2 x 50 mL R2)
D10707	Urea UV Auto, Urease / GLDH	5 x 50 mL (4 x 50 mL R1 + 2 x 25 mL R2)
402999	Urea, Urease /colorimetric	5 x 100 mL - 2 x 125 mL Reagent 1 - 3 x 83.3 mL Reagent 2 - 1 x 2.5 mL Reagent 3 - 1 x 3 mL Urea Standard
413925	Urea, Urease /colorimetric	6 x 25 mL - 3 x 25 mL Reagent 1 - 3 x 25 mL Reagent 2 - 1 x 0.75 mL Reagent 3 - 1 x 3 mL Urea Standard
D94710	Uric Acid AOX, Enzymatic, colorimetric	5 x 100 mL (4 x 100 mL R1 + 1 x 100 mL R2)
D98714	Uric Acid AOX, Enzymatic, colorimetric	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
D00719	Uric Acid AOX, Enzymatic, colorimetric	5 x 25 mL (4 x 25 mL R1 + 1 x 25 mL R2)
D00720	Uric Acid AOX, Enzymatic, colorimetric	5 x 10 mL (4 x 10 mL R1 + 1 x 10 mL R2)
D84911	Uric Acid AOX, Enzymatic, colorimetric	10 x 50 mL (10 x 40 mL R1 + 4 x 25 mL R2)
D0440917	Uric Acid AOX, Enzymatic, colorimetric	5 x 62.5 mL (4 x 62.5 mL R1 + 1 x 62.5 mL R2)
DA0846	Uric Acid AOX, Enzymatic, colorimetric	5 x 50 mL (5 x 40 mL R1 + 5 x 10 mL R2)
DT1046	Uric Acid AOX, Enzymatic, colorimetric	4 x 62.5 mL (4 x 50 mL R1 + 4 x 12.5 mL R2)
DK0743	Uric Acid AOX, Enzymatic, colorimetric	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
DE1846	Uric Acid AOX, Enzymatic, colorimetric	8 x 62.5 mL (8 x 50 mL R1 + 8 x 12.5 mL R2)
DB20334	Uric Acid AOX, Enzymatic, colorimetric	4 x 62.5 mL (4 x 50 mL R1 + 4 x 12.5 mL R2)
D03123B	Uric Acid TBHBA, Enzymatic, colorimetric	1 x 1.25 L (1 x 1 L R1 + 1 x 0.25 L R2)
D95459	Uric Acid TBHBA, Enzymatic, colorimetric	5 x 100 mL (4 x 100 mL R1 + 1 x 100 mL R2)
D98461	Uric Acid TBHBA, Enzymatic, colorimetric	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
D00463	Uric Acid TBHBA, Enzymatic, colorimetric	5 x 25 mL (4 x 25 mL R1 + 1 x 25 mL R2)
D00464	Uric Acid TBHBA, Enzymatic, colorimetric	5 x 10 mL (4 x 10 mL R1 + 1 x 10 mL R2)
D83911	Uric Acid TBHBA, Enzymatic, colorimetric	10 x 50 mL (10 x 40 mL R1 + 4 x 25 mL R2)
D0441917	Uric Acid TBHBA, Enzymatic, colorimetric	5 x 62.5 mL (4 x 62.5 mL R1 + 1 x 62.5 mL R2)
DA0847	Uric Acid TBHBA, Enzymatic, colorimetric	5 x 50 mL (5 x 40 mL R1 + 5 x 10 mL R2)
DT1047	Uric Acid TBHBA, Enzymatic, colorimetric	4 x 62.5 mL (4 x 50 mL R1 + 4 x 12.5 mL R2)
DK0744	Uric Acid TBHBA, Enzymatic, colorimetric	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
DE1847	Uric Acid TBHBA, Enzymatic, colorimetric	8 x 62.5 mL (8 x 50 mL R1 + 8 x 12.5 mL R2)
D10459	Uric Acid TBHBA, Enzymatic, colorimetric	5 x 100 mL (4 x 100 mL R1 + 2 x 50 mL R2)
D10461	Uric Acid TBHBA, Enzymatic, colorimetric	5 x 50 mL (4 x 50 mL R1 + 2 x 25 mL R2)
507201B	Zinc, 5-Br-PAPS	1 x 1 L
507240	Zinc, 5-Br-PAPS	5 x 25 mL
587911	Zinc, 5-Br-PAPS	5 x 50 mL
50446917	Zinc, 5-Br-PAPS	5 x 50 mL
5K0745	Zinc, 5-Br-PAPS	5 x 50 mL
5A0848	Zinc, 5-Br-PAPS	5 x 20 mL
5T1048	Zinc, 5-Br-PAPS	5 x 20 mL

5E1848 | Zinc, 5-Br-PAPS | 5 x 20 mL

Auxiliary Reagents, Supplements and Additives

REF	Product	Content
D96361	Pyridoxal-5'-Phosphate	1 x 4 mL
D96122B	Cholesterol HDL Precipitant	1 x 1 L
D14125	Cholesterol HDL Precipitant	5 x 100 mL
D00127	Cholesterol HDL Precipitant	5 x 50 mL
D00142	Cholesterol HDL Precipitant	5 x 25 mL
D00129	Cholesterol HDL Precipitant	5 x 10 mL
D13136	Cholesterol LDL Precipitant	5 x 100 mL
D13137	Cholesterol LDL Precipitant	5 x 50 mL
D13138	Cholesterol LDL Precipitant	5 x 25 mL
D13139	Cholesterol LDL Precipitant	5 x 10 mL

Calibrators

REF	Product	Content
D98485	Diacal Auto	5 x 3 mL
D98485SV	Diacal Auto	1 x 3 mL
D13585SV	Diacal Lipids	1 x 2 mL
D13595	Diacal CK-MB	5 x 1 mL
D13595SV	Diacal CK-MB	1 x 1 mL
913870SV	ADA Calibrator	1 x 1 mL
Y17565SV	G6PDH Calibrator	1 x 0,5 mL
908550	Homocysteine Calibrator Set (5 levels)	5 x 1 mL
Z05880	Ethanol Calibrator/Control Set	4 x 1 mL
F03710SV	HDL-Cholesterol Calibrator	1 x 3 mL
F03711SV	LDL-Cholesterol Calibrator	1 x 1 mL
Y04705SV	Hemoglobin Total Calibrator	1 x 2 mL

Standards

REF	Product	Content
D95555	Albumin Standard	1 x 3 mL
Y08310SV	Ammonia Standard	1 x 5 mL
903210	Bile Acids Standard	1 x 3 mL
D95094	Calcium Standard	1 x 3 mL
D95108	Chloride Standard	1 x 3 mL
D95114	Cholesterol Standard	1 x 3 mL
D06520SV	CO ₂ Standard	1 x 3 mL
507163SV	Copper Standard	1 x 3 mL
D94592	Creatinine Standard	1 x 3 mL
D95223	Glucose Standard	1 x 3 mL
D10090SV	beta-Hydroxybutyrate Standard	1 x 3 mL
D95305	Iron Standard	1 x 3 mL
910280	Lithium Standard Set (3 levels)	3 x 3 mL
D95339	Magnesium Standard	1 x 3 mL
D07963SV	NEFA Standard	1 x 3 mL
D95362	Phosphorus Standard	1 x 3 mL
910180	Potassium Standard Set (2 levels)	2 x 3 mL
D94683	Protein Total Standard	1 x 3 mL
D03600	Protein Total in Urine/CSF Standard	1 x 3 mL
909680	Sodium Standard Set (2 levels)	2 x 3 mL
D95380	Triglycerides Standard	1 x 3 mL
D95706	Urea Standard	1 x 3 mL
D94708	Uric Acid Standard	1 x 3 mL
507263SV	Zinc Standard	1 x 3 mL

Controls REF	Product	Content
D98481	Diacon N	12 x 5 mL
D14481	Diacon N	5 x 5 mL
D98481SV	Diacon N	1 x 5 mL
D98482	Diacon P	12 x 5 mL
D14482	Diacon P	5 x 5 mL
D98482SV	Diacon P	1 x 5 mL
D99486	Diacon Lipids	3 x 3 mL
D99486SV	Diacon Lipids	1 x 3 mL
D11487	Diacon Lipids High	3 x 3 mL
D11487SV	Diacon Lipids High	1 x 3 mL
D08581	Diacon Urine Level 1	12 x 5 mL
D08581SV	Diacon Urine Level 1	1 x 5 mL
D08582	Diacon Urine Level 2	12 x 5 mL
D08582SV	Diacon Urine Level 2	1 x 5 mL
913880	ADA Control Set (2 levels)	2 x 1 mL
Y08330	Ammonia Control Set (2 levels)	2 x 5 mL
D16525	CO2 Control	3 x 3 mL
D16525SV	CO2 Control	1 x 3 mL
Y17560	G6PDH Control Set (3 levels)	6 x 0,5 mL
Y04706	Hemoglobin Total Control Set (3 levels)	6 x 2 mL
905620	Homocysteine Control Set (4 levels)	4 x 1 mL
910290	Lithium Control Set (2 levels)	2 x 3 mL
910190	Potassium Control Set (2 levels)	2 x 3 mL

EC DECLARATION OF CONFORMITY

In accordance with Directive 98/79/EC

We, **PZ CORMAY S.A.**, 22 Wiosenna Str., 05-092 Lomianki, Poland, declare that the following devices:

Devices name: See ATTACHMENT 1

Catalogue number: See ATTACHMENT 1

(classified as other IVDD – all devices with exception of devices listed in List A and List B and self-testing devices) comply with essential requirements of the ANNEX I – Directive 98/79/EC and their conformity assessment has been made accordingly to the ANNEX III – Directive 98/79/EC.

The devices named above have been designed and manufactured according to the specifications:

EN 13612:2006	Performance evaluation of in vitro diagnostic medical devices.
EN ISO 14971:2012	Medical Devices – Application of risk management to medical devices.
EN ISO 15223-1:2021	Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements.
EN ISO 18113-2:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use.
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents.

PZ CORMAY S.A Quality Management System complies with requirements of ISO 9001:2015 and EN ISO 13485:2016 standards and has been approved by Lloyd's Register Quality Assurance Limited in the range concerning design, production and distribution of reagents of in vitro diagnostics for medical, industrial and scientific laboratories and design, production, sales and maintenance of in vitro diagnostic medical-devices.

Signature:

Flavio Finotello

Vice President of Management Board of

PZ CORMAY S.A.

Place: Lomianki

Signature:

Wojciech Suchowski

Vice President of Management Board of

PZ CORMAY S.A.

Date: 25 May 2022

No	Cat. No	Name
1	7-216	ACCENT-200 ALAT
2	7-238	ACCENT-200 ALBUMIN
3	7-212	ACCENT-200 ALP
4	7-222	ACCENT-200 ALPHA 1-ANTITRYPSIN
5	7-221	ACCENT-200 ALPHA 1-GLYCOPROTEIN ACID
6	7-255	ACCENT-200 AMYLASE
7	7-276	ACCENT-200 AMYLASE EPS
8	7-207	ACCENT-200 APOLIPOPROTEIN B
9	7-214	ACCENT-200 ASAT
10	7-240	ACCENT-200 ASO
11	7-248	ACCENT-200 BIL DIRECT
12	7-245	ACCENT-200 BIL TOTAL
13	7-198	ACCENT-200 BILE ACIDS
14	7-251	ACCENT-200 CALCIUM
15	7-247	ACCENT-200 CALCIUM ARSENAZO
16	7-218	ACCENT-200 CERULOPLASMIN
17	7-204	ACCENT-200 CHOL
18	7-256	ACCENT-200 CHOLINESTERASE
19	7-220	ACCENT-200 CK
20	7-227	ACCENT-200 CK-MB
21	7-211	ACCENT-200 COMPLEMENT C3
22	7-213	ACCENT-200 COMPLEMENT C4
23	7-277	ACCENT-200 CREA ENZYMATIC
24	7-233	ACCENT-200 CREATININE
25	7-225	ACCENT-200 CRP ULTRA
26	7-200	ACCENT-200 CYSTATIN C
27	7-246	ACCENT-200 D-DIMER
28	7-265	ACCENT-200 dTIBC
29	7-278	ACCENT-200 ETHANOL
30	7-230	ACCENT-200 FERRITIN
31	7-258	ACCENT-200 FERRUM
32	7-219	ACCENT-200 FIBRINOGEN
33	7-224	ACCENT-200 GGT

Signature:

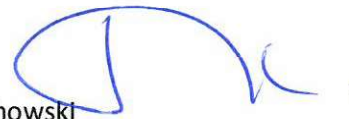


Flavio Finotello

Vice President of Management Board of
PZ CORMAY S.A.

Place: Lomianki

Signature:



Wojciech Suchowski

Vice President of Management Board of
PZ CORMAY S.A.

Date: 25 May 2022

No	Cat. No	Name
34	7-201	ACCENT-200 GLUCOSE
35	7-252	ACCENT-200 GLUCOSE HEX
36	7-215	ACCENT-200 HAPTOGLOBIN
37	7-111	ACCENT-200 HbA _{1c} DIRECT
38	7-279	ACCENT-200 HDL DIRECT
39	7-202	ACCENT-200 IgA
40	7-203	ACCENT-200 IgG
41	7-205	ACCENT-200 IgM
42	7-266	ACCENT-200 LACTATE
43	7-239	ACCENT-200 LDH
44	7-280	ACCENT-200 LDL DIRECT
45	7-209	ACCENT-200 LIPASE
46	7-290	ACCENT-200 LIPASE
47	7-228	ACCENT-200 LIPOPROTEIN (a)
48	7-229	ACCENT-200 MG
49	7-262	ACCENT-200 MG
50	7-244	ACCENT-200 MICROALBUMIN
51	7-226	ACCENT-200 MYOGLOBIN
52	7-243	ACCENT-200 PHOSPHORUS
53	7-237	ACCENT-200 RF
54	7-253	ACCENT-200 TG
55	7-273	ACCENT-200 TG mono
56	7-231	ACCENT-200 TOTAL IgE
57	7-236	ACCENT-200 TOTAL PROTEIN
58	7-210	ACCENT-200 TRANSFERRIN
59	7-208	ACCENT-200 UA
60	7-259	ACCENT-200 UIBC
61	7-206	ACCENT-200 UREA
62	7-242	ACCENT-200 URINE PROTEINS

Signature:

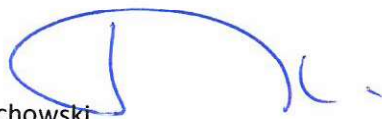


Flavio Finotello

Vice President of Management Board of
PZ CORMAY S.A.

Place: Lomianki

Signature:



Wojciech Suchowski

Vice President of Management Board of
PZ CORMAY S.A.

Date: 25 May 2022

EC DECLARATION OF CONFORMITY

In accordance with Directive 98/79/EC

We, **PZ CORMAY S.A.**, 22 Wiosenna Str., 05-092 Lomianki, Poland, declare that the following devices:

Devices name: See ATTACHMENT 1

Catalogue number: See ATTACHMENT 1

(classified as other IVDD – all devices with exception of devices listed in List A and List B and self-testing devices) comply with essential requirements of the ANNEX I – Directive 98/79/EC and their conformity assessment has been made accordingly to the ANNEX III – Directive 98/79/EC.

The devices named above have been designed and manufactured according to the specifications:

EN 13612:2006	Performance evaluation of in vitro diagnostic medical devices.
EN ISO 14971:2012	Medical Devices – Application of risk management to medical devices.
EN ISO 15223-1:2021	Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements.
EN ISO 18113-2:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use.
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents.

PZ CORMAY S.A Quality Management System complies with requirements of ISO 9001:2015 and EN ISO 13485:2016 standards and has been approved by Lloyd's Register Quality Assurance Limited in the range concerning design, production and distribution of reagents of in vitro diagnostics for medical, industrial and scientific laboratories and design, production, sales and maintenance of in vitro diagnostic medical-devices.

Signature:

Flavio Finotello

Vice President of Management Board of
PZ CORMAY S.A.

Place: Lomianki

Signature:

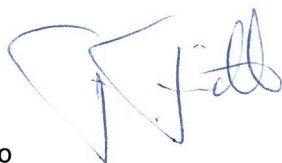
Wojciech Suchowski

Vice President of Management Board of
PZ CORMAY S.A.

Date: 25 May 2022

No	Cat. No	Name
1	4-289	CORMAY APOLIPOPROTEIN CALIBRATORS
2	4-278	CORMAY ASO CALIBRATOR
3	3-125	CORMAY BILE ACIDS CALIBRATOR
4	5-182	CORMAY CK-MB CALIBRATOR
5	4-276	CORMAY CRP ULTRA CALIBRATORS
6	5-185	CORMAY CYSTATIN C CALIBRATORS
7	4-259	CORMAY D-DIMER CALIBRATOR
8	5-105	CORMAY ETHANOL CALIBRATORS
9	5-106	CORMAY ETHANOL CALIBRATOR 100
10	4-491	CORMAY FERRITIN CALIBRATORS
11	4-292	CORMAY FIBRINOGEN CALIBRATOR
12	4-308	CORMAY HbA _{1c} DIRECT CALIBRATORS
13	5-178	CORMAY HDL/LDL CALIBRATOR
14	4-280	CORMAY IgE CALIBRATORS
15	4-287	CORMAY IMMUNO-MULTICAL
16	4-281	CORMAY Lp(a) CALIBRATORS
17	5-193	CORMAY MICROALBUMIN CALIBRATOR
18	5-174	CORMAY MULTICALIBRATOR LEVEL 1
19	5-176	CORMAY MULTICALIBRATOR LEVEL 1
20	5-175	CORMAY MULTICALIBRATOR LEVEL 2
21	5-177	CORMAY MULTICALIBRATOR LEVEL 2
22	4-279	CORMAY MYOGLOBIN CALIBRATORS
23	5-136	CORMAY PROCALCITONIN CALIBRATORS
24	4-277	CORMAY RF CALIBRATORS
25	5-181	CORMAY URINE PROTEINS CALIBRATORS

Signature:




Flavio Finotello

Vice President of Management Board of
PZ CORMAY S.A.

Place: Lomianki

Signature:



Wojciech Suchowski

Vice President of Management Board of
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EN ISO 18113-2:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use.
EN ISO 23640:2015-10	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents.

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Signature:



Flavio Finotello

Vice President of Management Board of
PZ CORMAY S.A.

Place: Lomianki

Signature:



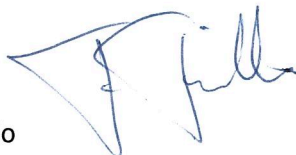
Wojciech Suchowski

Vice President of Management Board of
PZ CORMAY S.A.

Date: 9 May 2022

No	Cat. No	Name
1	5-163	CORMAY AMMONIA / ETHANOL CONTROLS
2	5-165	CORMAY AMMONIA/ETHANOL CONTROLS
3	4-293	CORMAY APOLIPOPROTEIN CONTROL
4	5-149	CORMAY BILE ACIDS CONTROLS
5	5-183	CORMAY CK-MB CONTROL N
6	5-184	CORMAY CK-MB CONTROL P
7	4-460	CORMAY CYSTATIN C CONTROLS
8	4-459	CORMAY D-DIMER CONTROLS
9	4-328	CORMAY HbA _{1c} DIRECT CONTROLS
10	4-288	CORMAY IMMUNO-CONTROL I
11	4-290	CORMAY IMMUNO-CONTROL II
12	4-291	CORMAY IMMUNO-CONTROL III
13	5-179	CORMAY LIPID CONTROL 1
14	5-180	CORMAY LIPID CONTROL 2
15	4-492	CORMAY Lp(a) CONTROL N
16	4-493	CORMAY Lp(a) CONTROL P
17	4-461	CORMAY MICROALBUMIN CONTROL
18	5-166	CORMAY PROCALCITONIN CONTROLS
19	5-172	CORMAY SERUM HN
20	5-173	CORMAY SERUM HP
21	5-161	CORMAY URINE CONTROL LEVEL 1
22	5-162	CORMAY URINE CONTROL LEVEL 2
23	5-164	CORMAY URINE CONTROLS
24	6-054	CORMAY URINALYSIS CONTROLS
25	6-056	CORMAY URINALYSIS CONTROLS

Signature:



Flavio Finotello

Vice President of Management Board of
PZ CORMAY S.A.

Place: Lomianki

Signature:



Wojciech Suchowski

Vice President of Management Board of
PZ CORMAY S.A.

Date: 9 May 2022



Zhejiang SKG Medical Technology Co., Ltd

Add: No.39, Anye Road, Gaoqiao Street, Huangyan, Taizhou, Zhejiang, China, 318020

Tel: 0086-576-84031666 Fax: 0086-576-84036668 Http://www.skgmed.com

CE Declaration of Conformity

Manufacturer: Zhejiang SKG Medical Technology Co., Ltd.

NO.39 Anye Road, Gaoqiao Street, Huangyan 318020 Taizhou, Zhejiang

PEOPLE'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

