

CA-GJLA202401260006

mindray

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

Date: 26.01.2024

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, 2024**. 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.

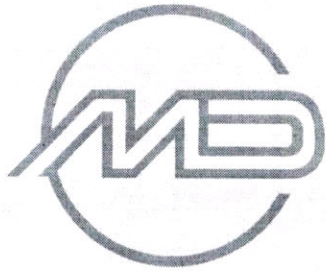
Best regards,



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

**SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.**
Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan,
Shenzhen 518057, P.R. China
Tel: +86 755 26582888
Fax: +86 755 26582680
Website: www.mindray.com





REGISTRATION NO. 04721Q10132R7L

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of

ShenZhenMindray Bio-Medical Electronics Co., Ltd.

Registered Address: Floor 1st-Floor 4th, Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, Shenzhen, P.R.China

Manufacturing Address: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, Shenzhen, P.R.China; 1203 Nanhuan Avenue, Guangming District, Shenzhen, P. R. China

Has been assessed and conformed to the following standard(s)

GB/T 19001-2016 idt ISO 9001:2015

The certificate is valid for the following scope:

The Design, Development, Production and Service of Endoscope light source ,Diagnostic Ultrasound System , Endoscope Camera System, Microplate washer , UltraSync, patient monitor, Center Monitoring System, Telemetry Monitoring System, Vital Signs Monitor, Pulse Oximeter, Vital Signs Monitor & Patient Monitors, Disposable SpO2 Sensor, SpO2 Sensor, ECG Cable, NIBP Cuff, Temperature Probe, Holter, Wearable ECG Monitor, Analysis system, Defibrillator/Monitor, Electrocardiograph, Anesthesia Machine, Ventilator, Ultrasound Diagnostic System, Digital Ultrasonic Diagnostic Imaging System, Ultrasound Imaging Administration System, Digital Radiography System, Mobile radiography system, Mobile Stand, Radiography Imaging Information System, retropad detector and its imaging system, Auto Hematology Analyzer, Urine Aplyzer, Auto Silde Maker&Statiner, Flow Cytometer, Automatic Glycohemoglobin Analyzer, Specific Protein Analyzer, Sample Processing System, Chemistry Analyzer, Semi-auto Chemistry Analyzer, Microplate reader, Chemiluminescence Immunoassay Analyzer, CPR sensor, VS-900 Neo Vital Signs Monitor, Automated External Defibrillator, Ultrasonic Transducer, Automated Digital Cell Morphology Analyzer and Vitro Diagnostic Reagent (within the scope of manufacturing license)

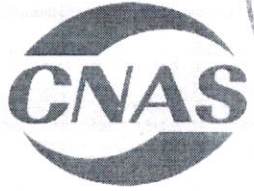
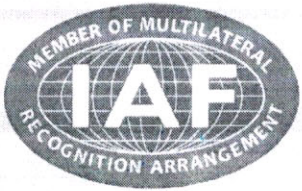
Date of issue: April 15,2021

Date of expiry: April 05,2024

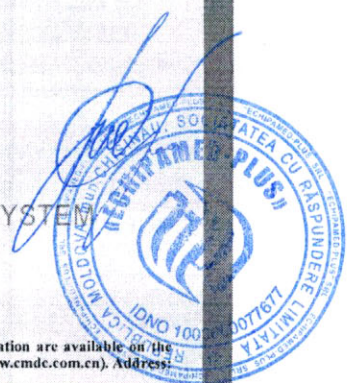
Date of change: May 31,2022

General Manager:

BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.



MANAGEMENT SYSTEM
CNAS C047-M



Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (<http://www.cnca.gov.cn>) or the website of CMD (<http://www.cmdc.com.cn>). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993



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)



ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFICADO ◆ CERTIFICAT



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)

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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

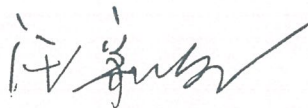
Classification: List A in IVDD annex II

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 (Bromcresol 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)

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

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

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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

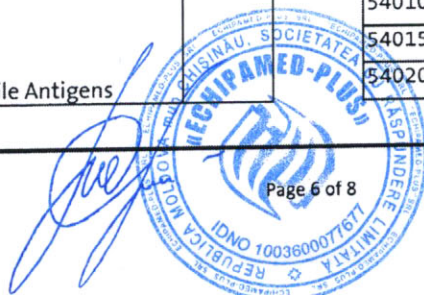


Cat.-no.	Product name	Class
16890	HumaStar 100	Others
16895	HumaStar 200	Others
16930	HumaStar 300SR	Others
16923/20	Cuvette Clean	Others
17200	ELISYS DUO	Others
17350	ELISYS UNO	Others
17400/10	HC-Diluent	Others
17400/11	HC-Diluent	Others
17400/20	HC-Lyse CF	Others
17400/22	HC-Lyse CF	Others
17400/30	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
19550P	Starter Kit 10, 100, 1000 Digital	Others
19150/10	Pipette Tips 5 ml white	Others
19160/10	Pipette Tips 10 ml white	Others
19320/10	Pipette Tips 300 µl white	Others
19320/20	Pipette Tips 20 µl crystal	Others
19910/20	Pipette Tips 200 µl yellow	Others
19920/40	Pipette Tips 1000 µl blue	Others
22002	Combina 9SG	Others
22022	Combina 2	Others
22032	Combina 3	Others
22092	Combina Glucose	Others
22102	Combina 10 M	Others
22132	Combina 13	Others
23111	Combina 11 S	Others
27032P	Hexagon Troponin	Others
28009	Hexagon OBTI	Others
28032	Hexagon PSA	II, B
28220	Hexagon OBTScreen	Others
29012	Hexagon IgE	Others
31002, 31003	HemoStat Thromboplastin-SI	Others
31012	HemoStat Thromboplastin ^{liquid}	Others
32002	HemoStat Fibrinogen	Others
33002, 33012 33013 33022	HemoStat aPTT-EL	Others
34002	HemoStat Thrombin Time	Others
35001, 35002	HemoStat Control Plasma (normal, abnormal)	Others
35500	HemoStat Calibrator	Others
36002	HemoStat D-Dimer	Others
36012	HemoStat D-Dimer Control high/low	Others
36102	HemoStat Antithrombin liquid	Others
40030, 40031	SLE Latex Test	Others
40037	Glycin-NaCl buffer	Others
40038, 40039	I.M. Quick	Others
40042, 40043, 40040	Humatex CRP	Others
40052, 40053, 40050	Humatex RF	Others
40062, 40063, 40060	Humatex ASO	Others
50001, 50002, 50016	Syphilis RPR	Others
50101	Syphilis TPHA	Others
50201, 50200, 50211, 50221, 50231, 50241,	HUMATEX Febrile Antigens	Others

Cat.-no.	Product name	Class
50251, 50261, 50271, 50281, 50291 50301		
51005	Syphilis Screen	Others
51015	IgE total ELISA	Others
51050	HBsAg ultra sens	II, A
51103	CMV IgM ELISA	II, B
51104	EBV IgM ELISA	Others
51106	Measles IgM ELISA	Others
51107	Mumps IgM ELISA	Others
51108	Rubella IgM µ-capture	II, B
51110	VZV IgM ELISA	Others
51119	Toxo IgM µ-capture ELISA	II, B
51126	HSV IgM ELISA	Others
51140	Dengue Virus IgM ELISA	Others
51150	Chagas Rec ELISA	Others
51203	CMV IgG ELISA	II, B
51204	EBV IgG ELISA	Others
51205C	anti-HIV ½ ELISA	II, A
51206	Measles IgG ELISA	Others
51207	Mumps IgG ELISA	Others
51208	Rubella IgG	II, B
51209	Toxoplasma g. IgG ELISA	II, B
51210	VZV IgG ELISA	Others
51215	HIV Ag/Ab ELISA	II, A
51216	HSV 1 IgG ELISA	Others
51222	H.Pylori IgG ELISA	Others
51226	HSV 2 IgG ELISA	Others
51228	Chlamydia Trachomatis IgG	II, B
51240	Dengue Virus IgG ELISA	Others
51275	Anti-HCV ELISA	II, A
51322	H.Pylori IgA ELISA	Others
51328	Chlamydia Trachomatis IgA	II, B
52010	AFP ELISA	Others
52020	CEA ELISA	Others
52030	PSA ELISA	II, B
52035	fPSA ELISA	II, B
52050	CA 125	Others
52060	CA 19-9	Others
52080	CA 15-3	Others
53010	LH ELISA	Others
53020	FSH ELISA	Others
53030	Prolactin ELISA	Others
53040	hCG ELISA	Others
54010	T3 ELISA	Others
54015	fT3 ELISA	Others
54020	T4 ELISA	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





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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


Devices 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 980:2008 | Graphical symbols for use in the labelling of medical devices. |
| EN 13612:2002 | Performance evaluation of in vitro diagnostic medical devices. |
| EN 13640:2002 | Stability testing of in vitro diagnostic reagents. |
| EN ISO 14971:2009 | Medical Devices – Application of risk management to medical devices. |
| EN ISO 18113-2:2009 | In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). In vitro diagnostic reagents for professional use. |

PZ CORMAY S.A Quality Management System complies with requirements of ISO 9001:2008 and ISO 13485:2003 standards and has been approved by Lloyd's Register Quality Assurance Limited in the range concerning design, manufacturing and distribution of in vitro diagnostic medical devices for medical, industrial and research laboratories and sale and service of medical equipment.

Signed by:.....


Name: Barbara Tuora-Wysocka

Position: Member of Management Board of PZ CORMAY S.A.

Place: Lublin

Date: 11 May 2012



ATTACHMENT 1

No	Cat. No	Name
1	7-249	ACCENT-200 ACP
2	7-216	ACCENT-200 ALAT
3	7-238	ACCENT-200 ALBUMIN
4	7-212	ACCENT-200 ALP
5	7-222	ACCENT-200 ALPHA 1-ANTITRYPSIN
6	7-221	ACCENT-200 ALPHA 1-GLYCOPROTEIN ACID
7	7-235	ACCENT-200 ALPHA 1-MICROGLOBULIN
8	7-232	ACCENT-200 ALPHA-FETOPROTEIN
9	7-255	ACCENT-200 AMYLASE
10	7-276	ACCENT-200 AMYLASE EPS
11	7-223	ACCENT-200 ANTITHROMBIN III
12	7-207	ACCENT-200 APOLIPOPROTEIN B
13	7-214	ACCENT-200 ASAT
14	7-240	ACCENT-200 ASO
15	7-248	ACCENT-200 BIL DIRECT
16	7-298	ACCENT-200 BIL DIRECT VANAD
17	7-245	ACCENT-200 BIL TOTAL
18	7-299	ACCENT-200 BIL TOTAL VANAD
19	7-198	ACCENT-200 BILE ACIDS
20	7-251	ACCENT-200 CALCIUM
21	7-247	ACCENT-200 CALCIUM ARSENAZO
22	7-218	ACCENT-200 CERULOPLASMIN
23	7-204	ACCENT-200 CHOL
24	7-256	ACCENT-200 CHOLINESTERASE
25	7-220	ACCENT-200 CK
26	7-227	ACCENT-200 CK-MB
27	7-211	ACCENT-200 COMPLEMENT C3
28	7-213	ACCENT-200 COMPLEMENT C4
29	7-277	ACCENT-200 CREA ENZYMATIC
30	7-233	ACCENT-200 CREATININE
31	7-225	ACCENT-200 CRP ULTRA
32	7-200	ACCENT-200 CYSTATIN C
33	7-246	ACCENT-200 D-DIMER
34	7-278	ACCENT-200 ETHANOL
35	7-230	ACCENT-200 FERRITIN
36	7-258	ACCENT-200 FERRUM
37	7-219	ACCENT-200 FIBRINOGEN
38	7-224	ACCENT-200 GGT
39	7-201	ACCENT-200 GLUCOSE
40	7-252	ACCENT-200 GLUCOSE HEX
41	7-215	ACCENT-200 HAPTOGLOBIN
42	7-111	ACCENT-200 HbA _{1c} DIRECT

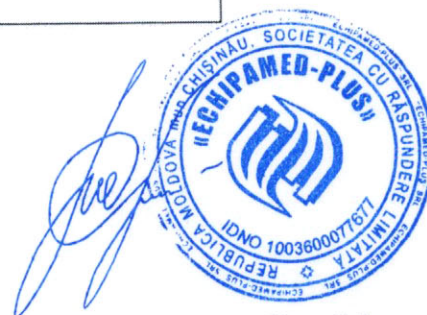
Signed by:.....

Name: Barbara Tuora-Wysocka

Position: Member of Management Board of PZ CORMAY S.A.

Place: Lublin

Date: 11 May 2012



ATTACHMENT 1

No	Cat. No	Name
43	7-241	ACCENT-200 HBDH
44	7-279	ACCENT-200 HDL DIRECT
45	7-202	ACCENT-200 IgA
46	7-203	ACCENT-200 IgG
47	7-205	ACCENT-200 IgM
48	7-266	ACCENT-200 LACTATE
49	7-239	ACCENT-200 LDH
50	7-280	ACCENT-200 LDL DIRECT
51	7-209	ACCENT-200 LIPASE
52	7-228	ACCENT-200 LIPOPROTEIN (a)
53	7-229	ACCENT-200 MG
54	7-262	ACCENT-200 MG
55	7-244	ACCENT-200 MICROALBUMIN
56	7-226	ACCENT-200 MYOGLOBIN
57	7-243	ACCENT-200 PHOSPHORUS
58	7-237	ACCENT-200 RF
59	7-253	ACCENT-200 TG
60	7-273	ACCENT-200 TG mono
61	7-231	ACCENT-200 TOTAL IgE
62	7-236	ACCENT-200 TOTAL PROTEIN
63	7-210	ACCENT-200 TRANSFERRIN
64	7-208	ACCENT-200 UA
65	7-263	ACCENT-200 UA PLUS
66	7-259	ACCENT-200 UIBC
67	7-206	ACCENT-200 UREA
68	7-242	ACCENT-200 URINE PROTEINS
69	3-109	ACCENT-200 ACID WASHING SOLUTION
70	3-108	ACCENT-200 ALKALINE WASHING SOLUTION
71	3-102	WASHING SOLUTION CONCENTRATE
72	3-103	WASHING SOLUTION CONCENTRATE

Signed by:.....

Name: Barbara Tuora-Wysocka

Position: Member of Management Board of PZ CORMAY S.A.

Place: Lublin

Date: 11 May 2012





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ISO 9001
Quality Management System



ISO 13485
Quality Management System

EC DECLARATION OF CONFORMITY

In accordance with Directive 98/79/EC

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

Devices name: see ATTACHMENT A

Devices number: see ATTACHMENT A

(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 conformity assessment made accordingly to the ANNEX III - Directive 98/79/EC.

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

EN ISO 14971:2000	Medical Devices – Application of risk management to medical devices.
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents.
EN 375:2001	Information supplied by the manufacturer with in vitro diagnostic reagents for professional use.
EN 980:2006	Graphical symbols for use in the labeling of medical devices.
EN 13640: 2002	Stability testing of in vitro diagnostic reagents.
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices.

PZ CORMAY S.A Quality Management System complies with requirements of ISO 9001:2008 and ISO 13485:2003 standard and has been approved by Lloyd's Register Quality Assurance Limited in the range concerning design, manufacturing and distribution of in vitro diagnostic medical devices for medical, industrial and research laboratories. Sale and service of medical equipment.

Signed by:

Name: Tomasz Tuora

Position: President PZ CORMAY S.A.

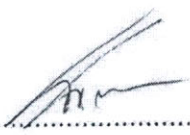
Place: Łomianki

Date: 16 September, 2010



Attachment A to the EC DECLARATION OF CONFORMITY

Device number	Device name
5-174	CORMAY MULTICALIBRATOR LEVEL 1
5-176	CORMAY MULTICALIBRATOR LEVEL 1
5-175	CORMAY MULTICALIBRATOR LEVEL 2
5-177	CORMAY MULTICALIBRATOR LEVEL 2
5-170	CORMAY MULTICAL
5-178	CORMAY HDL/LDL CALIBRATOR
4-287	CORMAY IMMUNO-MULTICAL
4-289	CORMAY APOLIPOPROTEIN CALIBRATORS
4-292	CORMAY FIBRINOGEN CALIBRATOR
4-295	CORMAY CRP NORMAL CALIBRATOR
4-276	CORMAY CRP ULTRA CALIBRATORS
4-279	CORMAY MYOGLOBIN CALIBRATORS
4-281	CORMAY Lp(a) CALIBRATORS
4-491	CORMAY FERRITIN CALIBRATORS
4-280	CORMAY IgE CALIBRATORS
4-282	CORMAY AFP CALIBRATORS
4-283	CORMAY BETA 2-MGLOB CALIBRATORS (S)
4-284	CORMAY BETA 2-MGLOB CALIBRATORS (U)
4-286	CORMAY ALPHA 1-MGLOB CALIBRATORS (S)
4-285	CORMAY ALPHA 1-MGLOB CALIBRATORS (U)
4-277	CORMAY RF CALIBRATORS
4-278	CORMAY ASO CALIBRATOR
4-318	CORMAY HbA1c CALIBRATORS
4-308	CORMAY HbA1c DIRECT CALIBRATORS
5-182	CORMAY CK-MB CALIBRATOR
4-259	CORMAY D-DIMER CALIBRATOR
5-181	CORMAY URINE PROTEINS CALIBRATORS
5-185	CORMAY CYSTATIN C CALIBRATORS
5-105	CORMAY ETHANOL CALIBRATORS
5-106	CORMAY ETHANOL CALIBRATOR 100
5-112	CORMAY CARBAMAZEPINE CALIBRATORS
5-114	CORMAY DIGITOXIN CALIBRATORS
5-113	CORMAY DIGOXIN CALIBRATORS
5-110	CORMAY GENTAMICIN CALIBRATORS
5-111	CORMAY PHENOBARBITAL CALIBRATORS
5-109	CORMAY THEOPHYLLINE CALIBRATORS
4-380	CORMAY BILIRUBIN CALIBRATOR

Signed by: 

Name: Tomasz Tuora

Position: President PZ CORMAY S.A.

Place: Łomianki

Date: 16 September, 2010





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EC DECLARATION OF CONFORMITY

In accordance with Directive 98/79/EC

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

Devices name: see ATTACHMENT A

Devices number: see ATTACHMENT A

(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 conformity assessment made accordingly to the ANNEX III - Directive 98/79/EC.

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EN 375:2001	Information supplied by the manufacturer with in vitro diagnostic reagents for professional use.
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EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices.

PZ CORMAY S.A Quality Management System complies with requirements of ISO 9001:2008 and ISO 13485:2003 standard and has been approved by Lloyd's Register Quality Assurance Limited in the range concerning design, manufacturing and distribution of in vitro diagnostic medical devices for medical, industrial and research laboratories. Sale and service of medical equipment.

Signed by:.....

Name: Tomasz Tuora

Position: President PZ CORMAY S.A.

Place: Łomianki

Date: 08 January, 2010



Attachment A to the EC DECLARATION OF CONFORMITY

Device number	Device name
5-172	CORMAY SERUM HN
5-173	CORMAY SERUM HP
4-288	CORMAY IMMUNO-CONTROL I
4-290	CORMAY IMMUNO-CONTROL II
4-291	CORMAY IMMUNO-CONTROL III
4-492	CORMAY Lp (a) CONTROL N
4-493	CORMAY Lp (a) CONTROL P
5-179	CORMAY LIPID CONTROL 1
5-180	CORMAY LIPID CONTROL 2
4-319	CORMAY HbA1c CONTROLS
4-328	CORMAY HbA1c DIRECT CONTROLS
4-293	CORMAY APOLIPOPROTEIN CONTROL
4-459	CORMAY D-DIMER CONTROLS
5-183	CORMAY CK-MB CONTROL N
5-184	CORMAY CK-MB CONTROL P
5-161	CORMAY URINE CONTROL LEVEL 1
5-162	CORMAY URINE CONTROL LEVEL 2
4-460	CORMAY CYSTATIN C CONTROLS
5-163	CORMAY AMMONIA/ETHANOL CONTROLS
5-108	CORMAY DIGITOXIN CONTROLS
5-107	CORMAY TDM CONTROLS

Signed by:.....

Name: Tomasz Tuora

Position: President PZ CORMAY S.A.

Place: Lomianki

Date: 08 January, 2010





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

Date, 2022-03-17

C. Dicks

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: ./.



DECLARATION OF CONFORMITY

We



Dialab Produktion und Vertrieb von chemisch – technischen Produkten und
Laborinstrumenten Gesellschaft m. b. H.
IZ-NÖ Süd, Hondastrasse, Objekt M55
2351 Wiener Neudorf, Austria

declare, on our own responsibility, that our products specified in the enclosed
addendum “Devices other than those covered by Annex II (Clinical Chemistry)”,
Rev.18 (8 pages),
classified as follows according to the directive on in vitro diagnostic medical
devices 98/79/EC:

Devices other than those covered by Annex II (Clinical Chemistry)

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

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

This Declaration is valid until 2022-03-28

Wr. Neudorf, 2019-04-04



Marlene Ramsey
Marlene Ramsey
Managing Director

Addendum to the Declaration of Conformity for Devices other than those covered by Annex II (Clinical Chemistry)



CLINICAL CHEMISTRY

Reagents

	REF	CONT		REF	CONT	
Adenosine Deaminase (ADA), Enzymatic, colorimetric	913816	6 x 25 ml				
	913813	3 x 25 ml				
	917810	3 x 10 ml				
Albumin, BCG	D97202B	1 x 1 L				
	D09550	4 x 250 ml				
	D97203	5 x 100 ml				
	D00204	5 x 50 ml				
	D00205	5 x 25 ml	alpha-Amylase,	397756B	1 x 1 L	
	D00206	5 x 10 ml	CNP-G3	397758	5 x 100 ml	
	D51911	10 x 50 ml		397759	5 x 50 ml	
	D0401917	9 x 65 ml		300760	5 x 25 ml	
	DK0701	5 x 50 ml		396754	5 x 10 ml	
	DA0801	5 x 50 ml		355911	10 x 50 ml	
	DT1001	4 x 50 ml		D0405917	9 x 65 ml	
	DE1801	10 x 50 ml		3K0704	5 x 50 ml	
				3A0805	5 x 20 ml	
				3T1005	5 x 20 ml	
			3E1805	5 x 20 ml		
Alkaline Phosphatase, mod. IFCC	D03101B	1 x 1,25 L				
	D95564	5 x 100 ml				
	D95565	5 x 50 ml				
	D00523	5 x 25 ml	alpha-Amylase Pancreatic,	D00582	5 x 100 ml	
	D00524	5 x 10 ml	ET-G7PNP	D94577	5 x 50 ml	
	D52911	10 x 50 ml		D00590	5 x 25 ml	
	D0402917	5 x 62,5 ml		D96568	5 x 10 ml	
	DK0703	5 x 50 ml		D56911	5 x 50 ml	
	DA0803	5 x 50 ml		D0404917	5 x 50 ml	
	DT1003	4 x 62,5 ml		DK0706	5 x 50 ml	
	DE1803	2 x 62,5 ml		DA0807	5 x 20 ml	
				DT1007	5 x 20 ml	
				DE1807	1 x 62,5 ml	
Alkaline Phosphatase, opt. DGKC	D03102B	1 x 1,25 L				
	D95560	5 x 100 ml				
	D95561	5 x 50 ml	Ammonia	N08160	5 x 10 ml	
	D00568	5 x 25 ml	Enzymatic, UV	N49911	1 x 50 ml	
	D00569	5 x 10 ml		NA0804	5 x 20 ml	
	D53911	10 x 50 ml		NT1004	5 x 20 ml	
	D0403917	5 x 62,5 ml		NE1804	5 x 20 ml	
	DK0702	5 x 50 ml				
	DA0802	5 x 50 ml	Bile Acids,	903110	5 x 100 ml	
	DT1002	4 x 62,5 ml	Enzymatic cycling	903115	5 x 50 ml	
	DE1802	2 x 62,5 ml		903120	5 x 25 ml	
				903125	5 x 10 ml	
				950911	5 x 50 ml	
				90410917	4 x 60 ml	
			9K0707	5 x 50 ml		
			9A0808	4 x 20 ml		
			9T1008	4 x 20 ml		
			9E1808	2 x 50 ml		
alpha-Amylase, mod. IFCC	D03103B	1 x 1,25 L				
	D94570	5 x 100 ml				
	D94571	5 x 50 ml				
	D00578	5 x 25 ml				
	D96569	5 x 10 ml				
	D54911	5 x 50 ml				
	D0406917	5 x 62,5 ml				
	DK0705	5 x 50 ml				
	DA0806	5 x 20 ml				
	DT1006	5 x 20 ml				
	DE1806	2 x 62,5 ml				



Addendum to the Declaration of Conformity for Devices other than those covered by Annex II (Clinical Chemistry)



	REF	CONT
Bilirubin Auto Direct, DCA	D03104B	1 x 1,25 L
	D96543	5 x 100 ml
	D96544	5 x 50 ml
	D00547	5 x 25 ml
	D00548	5 x 10 ml
	D58911	10 x 50 ml
	D0408917	5 x 62,5 ml
	DK0708	5 x 50 ml
	DA0809	5 x 50 ml
	DT1009	4 x 62,5 ml
	DE1809	4 x 62,5 ml

	REF	CONT
Bilirubin Auto Total, DCA	D03105B	1 x 1,25 L
	D96531	5 x 100 ml
	D96532	5 x 50 ml
	D00535	5 x 25 ml
	D00536	5 x 10 ml
	D57911	10 x 50 ml
	D0409917	5 x 62,5 ml
	DK0709	5 x 50 ml
	DA0810	5 x 50 ml
	DT1010	4 x 62,5 ml
	DE1810	4 x 62,5 ml

	REF	CONT
Bilirubin Direct, Jendrassik Grof	103106B	1 x 1,04 L
	102002	5 x 100 ml
	102012	5 x 50 ml
	113022	5 x 25 ml

	REF	CONT
Bilirubin Total, Jendrassik Grof	103107B	1 x 1,04 L
	102001	5 x 100 ml
	102011	5 x 50 ml
	116021	5 x 25 ml

	REF	CONT
Bilirubin Direct/Total, Jendrassik Grof	103200	4 x 100 ml
	103210	4 x 50 ml
	116320	4 x 25 ml

	REF	CONT
Carbon Dioxide (CO2), PEP-C	N03122B	1 x 1 L
	N00043/20	5 x 50 ml
	N88911	5 x 50 ml
	N0414917	9 x 65 ml
	NK0712	5 x 50 ml
	NA0820	5 x 20 ml
	NT1020	5 x 20 ml
	NE1820	5 x 20 ml

	REF	CONT
Calcium, Arsenazo	D01372B	1 x 1 L
	D01376	5 x 100 ml
	D01375	5 x 50 ml
	D01377	5 x 25 ml
	D01378	5 x 10 ml
	D59911	10 x 50 ml
	D0412917	9 x 65 ml
	DK0710	5 x 50 ml
	DA0811	5 x 50 ml
	DT1011	4 x 50 ml
	DT1311	5 x 20 ml
	DE1811	5 x 20 ml

	REF	CONT
Calcium, CPC	D03108B	1 x 1,25 L
	D99097	5 x 100 ml
	D95098	5 x 50 ml
	D00102	5 x 25 ml
	D00100	5 x 10 ml
	D60911	10 x 50 ml
	D0413917	5 x 62,5 ml
	DK0711	5 x 50 ml
	DA0812	5 x 50 ml
	DT1012	4 x 62,5 ml
DE1812	2 x 62,5 ml	

	REF	CONT
Chloride, Mercuric thiocyanate	D01222B	1 x 1 L
	D01223	5 x 100 ml
	D01225	5 x 50 ml
	D01227	5 x 25 ml
	D01228	5 x 10 ml
	D61911	10 x 50 ml
	D0415917	9 x 65 ml
	DK0713	5 x 50 ml
	DA0813	5 x 50 ml
	DT1013	4 x 50 ml
DT1313	5 x 20 ml	
DE1813	5 x 20 ml	

	REF	CONT
Cholesterol, CHOD-PAP	D96112B	1 x 1 L
	D08115	4 x 250 ml
	D95116	5 x 100 ml
	D98118	5 x 50 ml
	D00119	5 x 25 ml
	D00123	5 x 10 ml
	D62911	10 x 50 ml
	D0418917	9 x 65 ml
	DK0714	5 x 50 ml
	DA0814	5 x 50 ml
DT1014	4 x 50 ml	
DE1814	10 x 50 ml	

	REF	CONT
Cholesterol HDL Direct, Immuno-inhibition	F03120B	1 x 1,25 L
	F03100	5 x 100 ml
	F03101	5 x 100 ml
	F03115	5 x 50 ml
	F03116	5 x 25 ml
	F03117	5 x 10 ml
	F16911	5 x 50 ml
	F0416917	5 x 62,5 ml
	FK0715	5 x 50 ml
	FA0815	5 x 50 ml
	FT1015	4 x 62,5 ml
	FE1815	4 x 62,5 ml



Addendum to the Declaration of Conformity for Devices other than those covered by Annex II (Clinical Chemistry)



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	REF	CONT
Cholesterol LDL Direct, <i>Enzymatic selective protection</i>	F05126B	1 x 1,25 L
	F05365	5 x 50 ml
	F05366	5 x 25 ml
	F05367	5 x 10 ml
	F19911	5 x 50 ml
	F14911	1 x 50 ml
	F0417917	5 x 20 ml
	F0443917	5 x 62,5 ml
	FK0716	5 x 50 ml
	FA0816	5 x 20 ml
	FT1016	5 x 20 ml
	FT1616	4 x 62,5 ml
	FE1816	2 x 62,5 ml

Cholinesterase, <i>opt. DGKC</i>	D07710B	1 x 1,25 L
	D07720	5 x 100 ml
	D07730	5 x 50 ml
	D07740	5 x 25 ml
	D07750	5 x 10 ml
	D63911	5 x 50 ml
	D0419917	5 x 62,5 ml
	DK0717	5 x 50 ml
	DA0817	5 x 50 ml
	DT1017	4 x 62,5 ml
DE1817	2 x 62,5 ml	

CK-MB, <i>opt. DGKC / IFCC</i>	D10580B	1 x 12,5 L
	D10582B	1 x 1 L
	D10585	5 x 100 ml
	D10586	5 x 50 ml
	D10587	5 x 25 ml
	D10588	5 x 10 ml
	D35911	5 x 50 ml
	D0450917	5 x 62,5 ml
	DK1018	5 x 50 ml
	DA1018	5 x 20 ml
	DT1018	5 x 20 ml
	DE1818	2 x 62,5 ml
	D00589	5 x 25 ml
	D98589	5 x 10 ml

CK-NAC, <i>opt. DGKC / IFCC</i>	D03109B	1 x 1,25 L
	D00591	5 x 100 ml
	D94581	5 x 50 ml
	D00592	5 x 25 ml
	D98579	5 x 10 ml
	D64911	5 x 50 ml
	D0421917	5 x 62,5 ml
	DK0719	5 x 50 ml
	DA0819	5 x 50 ml
	DT1019	4 x 62,5 ml
	DE1819	2 x 62,5 ml

	REF	CONT
Copper, <i>3,5-DiBr-PAESA</i>	507101B	1 x 1 L
	507140	5 x 25 ml
	545911	5 x 50 ml
	50447917	5 x 50 ml
	5K0720	5 x 50 ml
	5A0821	5 x 20 ml
	5T1221	4 x 50 ml
Creatinine, <i>Enzymatic, PAP</i>	5T1021	5 x 20 ml
	5E1821	5 x 20 ml
	D11112B	1 x 1 L
	D06420	4 x 100 ml
	D06430	4 x 50 ml
	D06440	4 x 25 ml
Creatinine, <i>mod. Jaffe</i>	D06450	4 x 10 ml
	D69911	4 x 50 ml
	D0411917	4 x 50 ml
	DK0721	5 x 40 ml
	DA0822	5 x 50 ml
	DT1022	4 x 50 ml
	DE1822	4 x 50 ml
	D03111B	1 x 1,25 L
	D95595	5 x 100 ml
	D10595	5 x 100 ml
	D00616	5 x 50 ml
	D00617	5 x 25 ml
D00618	5 x 10 ml	
Ethanol, <i>Enzymatic, UV</i>	D66911	10 x 50 ml
	D0422917	5 x 62,5 ml
	DK0722	5 x 50 ml
	DA0823	5 x 50 ml
	DT1023	4 x 62,5 ml
	DE1823	4 x 62,5 ml
	D07830	5 x 50 ml
	D07840	5 x 25 ml
	D07850	5 x 10 ml
	D67911	5 x 50 ml
D0407917	5 x 50 ml	
	DK0723	5 x 50 ml
	DA0824	5 x 20 ml
	DT1024	5 x 20 ml
	DE1824	2 x 62,5 ml



Addendum to the Declaration of Conformity for Devices other than those covered by Annex II (Clinical Chemistry)



	REF	CONT
Fructosamine, NBT	310110B	1 x 1 L
	310140	2 x 20 ml
	310144	4 x 20 ml
G6PDH, UV, kinetic	Y04500	10 x 18 ml
Gamma GT, Szasz, standardized to IFCC	D03113B	1 x 1,25 L
	D00628	5 x 100 ml
	D95604	5 x 50 ml
	D00629	5 x 25 ml
	D98631	5 x 10 ml
	D68911	5 x 50 ml
	D0423917	5 x 62,5 ml
	DK0724	5 x 50 ml
	DA0825	5 x 50 ml
	DT1025	4 x 62,5 ml
	DE1825	2 x 62,5 ml
GLDH, DGKC	D03774	5 x 100 ml
	D03773	5 x 50 ml
	D03775	5 x 25 ml
	D03776	5 x 10 ml
	D03911	5 x 50 ml
	D0424917	5 x 50 ml
	DK0725	5 x 50 ml
	DA0826	5 x 20 ml
	DT1026	5 x 20 ml
	DE1826	1 x 62,5 ml
Glucose, GOD-PAP	D95218B	1 x 1 L
	D08220	4 x 250 ml
	D00221	5 x 100 ml
	D98221	5 x 50 ml
	D00223	5 x 25 ml
	D00224	5 x 10 ml
	D70911	10 x 50 ml
	D0425917	9 x 65 ml
	DK0726	5 x 50 ml
	DA0827	5 x 50 ml
	DT1027	4 x 50 ml
	DE1827	10 x 50 ml
	Glucose, Hexokinase	D03114B
D96226		5 x 100 ml
D96227		5 x 50 ml
D00632		5 x 25 ml
D00637		5 x 10 ml
D71911		5 x 50 ml
D0426917		5 x 62,5 ml
DK0727		5 x 50 ml
DA0828		5 x 50 ml
DT1028		4 x 62,5 ml
DE1828		8 x 62,5 ml

	REF	CONT
GOT (AST), mod. IFCC	D03115B	1 x 1,25 L
	D94610	5 x 100 ml
	D10610	5 x 100 ml
	D98616	5 x 50 ml
	D10616	5 x 50 ml
	D00678	5 x 25 ml
	D98617	5 x 10 ml
	D72911	10 x 50 ml
	D0427917	5 x 62,5 ml
	DK0728	5 x 50 ml
	DA0829	5 x 50 ml
GPT (ALT), mod. IFCC	DT1029	4 x 62,5 ml
	DE1829	4 x 62,5 ml
	D03116B	1 x 1,25 L
	D94620	5 x 100 ml
	D10620	5 x 100 ml
	D98624	5 x 50 ml
	D10624	5 x 50 ml
	D00640	5 x 25 ml
	D98625	5 x 10 ml
	D73911	10 x 50 ml
	D0428917	5 x 62,5 ml
alpha-HBDH, opt. DGKC	DK0729	5 x 50 ml
	DA0830	5 x 50 ml
	DT1030	4 x 62,5 ml
	DE1830	4 x 62,5 ml
	D96635	5 x 50 ml
	D00642	5 x 25 ml
	D00643	5 x 10 ml
	D74911	5 x 50 ml
	D0429917	5 x 62,5 ml
	DK0730	5 x 50 ml
	DA0831	5 x 20 ml
Homocysteine, Enzymatic cycling	DT1031	5 x 20 ml
	DE1831	1 x 62,5 ml
	908510	4 x 20 ml
	908520	4 x 10 ml
	992911	1 x 39 ml
	9A0849	4 x 20 ml
9T1049	4 x 20 ml	
9E1849	2 x 39 ml	



Addendum to the Declaration of Conformity for Devices other than those covered by Annex II (Clinical Chemistry)



	REF	CONT
Hemoglobin Total, Cyanmethemoglobin	Y04704B	1 x 1 L
	Y04701	5 x 100 ml
	Y04702	5 x 50 ml
beta-Hydroxybutyrate Enzymatic, UV	D18027	5 x 25 ml
	D18028	5 x 10 ml
	D42911	1 x 50 ml
	DA1832	5 x 20 ml
	DT1832	5 x 20 ml
	DE1832	1 x 62,5 ml

Iron, Ferene	D03118B	1 x 1,25 L
	D01103	5 x 100 ml
	D01104	5 x 50 ml
	D01105	5 x 25 ml
	D01106	5 x 10 ml
	D91911	10 x 50 ml
	D0430917	5 x 62,5 ml
	DK0732	5 x 50 ml
	DA0833	5 x 50 ml
	DT1033	4 x 62,5 ml
DE1833	2 x 62,5 ml	

Lactate Enzymatic, UV	D08110B	1 x 1 L
	D08130	5 x 50 ml
	D08140	5 x 25 ml
	D14150	5 x 10 ml
	D75911	5 x 50 ml
	D0445917	5 x 50 ml
	DK1431	5 x 50 ml
	DA0834	5 x 20 ml
	DT1034	5 x 20 ml
	DE1834	2 x 62,5 ml

LDH-L, IFCC	D03300B	1 x 1,25 L
	D00662	5 x 100 ml
	D00663	5 x 50 ml
	D00664	5 x 25 ml
	D00665	5 x 10 ml
	D89911	5 x 50 ml
	D0431917	5 x 62,5 ml
	DK0733	5 x 50 ml
	DA0835	5 x 50 ml
	DT1035	4 x 62,5 ml
DE1835	2 x 62,5 ml	

LDH-P, opt. DGKC	D03119B	1 x 1,25 L
	D00656	5 x 100 ml
	D94651	5 x 50 ml
	D00657	5 x 25 ml
	D00658	5 x 10 ml
	D76911	5 x 50 ml
	D0432917	5 x 62,5 ml
	DK0734	5 x 50 ml
	DA0836	5 x 50 ml
	DT1036	4 x 62,5 ml
DE1836	2 x 62,5 ml	

	REF	CONT
Lipase, Enzymatic, colorimetric	D01441	5 x 50 ml
	D01440	5 x 25 ml
	D01443	5 x 10 ml
	D44911	5 x 50 ml
	D0433917	5 x 50 ml
	DK0735	5 x 50 ml
	DA0837	5 x 20 ml
	DT1037	5 x 20 ml
DE1837	2 x 62,5 ml	

Lithium Enzymatic	910210	3 x 20 ml
	9A0850	3 x 20 ml
	9T1050	3 x 20 ml
	947911	1 x 60 ml
	9E1850	1 x 60 ml

Magnesium, Xylidyl blue	D01241B	1 x 1 L
	D01243	5 x 100 ml
	D01245	5 x 50 ml
	D01256	5 x 25 ml
	D01246	5 x 10 ml
	D78911	10 x 50 ml
	D0434917	9 x 65 ml
	DK0736	5 x 50 ml
	DA0838	5 x 50 ml
	DT1038	4 x 50 ml
DE1838	5 x 20 ml	

NEFA, ACOD-PAP	D07940	5 x 25 ml
	D07950	5 x 10 ml
	D77911	1 x 50 ml
	D0443917	5 x 50 ml
	DK0948	5 x 50 ml
	DA0839	5 x 20 ml
	DT1039	5 x 20 ml
	DE1839	1 x 62,5 ml

Phosphorus Inorganic, Molybdate	D00359B	1 x 1 L
	D00361	5 x 100 ml
	D00362	5 x 50 ml
	D00363	5 x 25 ml
	D00364	5 x 10 ml
	D85911	10 x 50 ml
	D0435917	9 x 65 ml
	DK0737	5 x 50 ml
	DA0840	5 x 50 ml
	DT1040	4 x 50 ml
DT1340	5 x 20 ml	
DE1840	5 x 20 ml	



Addendum to the Declaration of Conformity for Devices other than those covered by Annex II (Clinical Chemistry)



	REF	CONT
Potassium, <i>Enzymatic</i>	914105	5 x 100 ml
	914106	5 x 50 ml
	914107	5 x 25 ml
	910110	5 x 10 ml
	948911	1 x 50 ml
	9A0851	5 x 20 ml
	9T1051	5 x 20 ml
	9E1851	2 x 62,5 ml

	REF	CONT
Protein Total, <i>Biuret</i>	D03120B	1 x 1,25 ml
	D95680	5 x 100 ml
	D00685	5 x 50 ml
	D00686	5 x 25 ml
	D00687	5 x 10 ml
	D80911	10 x 50 ml
	D0437917	5 x 62,5 ml
	DK0738	5 x 50 ml
	DA0841	5 x 50 ml
	DT1041	4 x 62,5 ml
	DE1841	8 x 62,5 ml

	REF	CONT
Protein Total Mono, <i>Biuret</i>	D12681B	1 x 1 L
	D12680	5 x 100 ml
	D13685	5 x 50 ml
	D13686	5 x 25 ml
	D13687	5 x 10 ml
	D43911	10 x 50 ml
	D0448917	9 x 65 ml
	DA1353	5 x 50 ml
	DT1353	4 x 50 ml
	DK1346	5 x 50 ml
	DE1853	10 x 50 ml

	REF	CONT
Protein Total in Urine/CSF, <i>Pyrogallol red</i>	D03127B	1 x 1 L
	D03200	5 x 25 ml
	D79911	5 x 50 ml
	D0436917	9 x 65 ml
	DK0739	5 x 50 ml
	DA1042	5 x 20 ml
	DT1042	5 x 20 ml
	DE1842	5 x 20 ml

	REF	CONT
Triglycerides, <i>GPO-PAP</i>	D98386B	1 x 1 L
	D08388	4 x 250 ml
	D00389	5 x 100 ml
	D96388	5 x 50 ml
	D00390	5 x 25 ml
	D98390	5 x 10 ml
	D81911	10 x 50 ml
	D0438917	9 x 65 ml
	DK0740	5 x 50 ml
	DA0843	5 x 50 ml
	DT1043	4 x 50 ml
	DE1843	10 x 50 ml

	REF	CONT
Sodium, <i>Enzymatic</i>	914605	5 x 100 ml
	914607	6 x 25 ml
	909610	3 x 20 ml
	990911	1 x 60 ml
	9A0852	3 x 20 ml
	9T1052	3 x 20 ml
9E1852	2 x 60 ml	

	REF	CONT
UIBC, <i>Ferene</i>	D07300B	1 x 12,5 L
	D07310B	1 x 1 L
	D07320	5 x 100 ml
	D07330	5 x 50 ml
	D07340	5 x 25 ml
	D07350	5 x 10 ml
	D86911	5 x 50 ml
	D0444917	5 x 62,5 ml
	D1444917	350 ml
	DK0741	5 x 50 ml
	DA0844	5 x 50 ml
	DT1044	4 x 62,5 ml
	DE1844	2 x 62,5 ml

	REF	CONT
Urea UV Auto, <i>Urease/GLDH</i>	D03121B	1 x 1,25 L
	D95704	5 x 100 ml
	D10704	5 x 100 ml
	D98707	5 x 50 ml
	D10707	5 x 50 ml
	D00715	5 x 25 ml
	D00716	5 x 10 ml
	D82911	10 x 50 ml
	D0439917	5 x 62,5 ml
	DK0742	5 x 50 ml
	DA0845	5 x 50 ml
	DT1045	4 x 62,5 ml
	DE1845	4 x 62,5 ml

	REF	CONT
Urea, <i>Urease/colorimetric</i>	402999	5 x 100 ml
	413925	6 x 25 ml

	REF	CONT
Uric Acid AOX, <i>Enzymatic, colorimetric</i>	D94710	5 x 100 ml
	D98714	5 x 50 ml
	D00719	5 x 25 ml
	D00720	5 x 10 ml
	D84911	10 x 50 ml
	D0440917	5 x 62,5 ml
	DK0743	5 x 50 ml
	DA0846	5 x 50 ml
	DT1046	4 x 62,5 ml
	E1846	8 x 62,5 ml



Addendum to the Declaration of Conformity for Devices other than those covered by Annex II (Clinical Chemistry)



	REF	CONT
Uric Acid TBHBA, Enzymatic, colorimetric	D03123B	1 x 1,25 L
	D95459	5 x 100 ml
	D10459	5 x 100 ml
	D98461	5 x 50 ml
	D10461	5 x 50 ml
	D00463	5 x 25 ml
	D00464	5 x 10 ml
	D83911	10 x 50 ml
	D0441917	5 x 62,5 ml
	DK0744	5 x 50 ml
	DA0847	5 x 50 ml
	DT1047	4 x 62,5 ml
	DE1847	8 x 62,5 ml
	Zinc 5-Br-PAPS	507201B
507240		5 x 25 ml
587911		5 x 50 ml
50446917		5 x 50 ml
5K0745		5 x 50 ml
5A0848		5 x 20 ml
5T1048		5 x 20 ml
5E1848		5 x 20 ml

	REF	CONT
Auxiliary Reagents, Supplements and Additives		
	REF	CONT
G6PDH Lyse Reagent	Y04550LV	1 x 60 ml
Pyridoxal-5'-Phosphate	D96361	1 x 4 ml
Cholesterol HDL Precipitant	D96122B	1 x 1 L
	D14125	5 x 100 ml
	D00127	5 x 50 ml
	D00142	5 x 25 ml
	D00129	5 x 10 ml
Cholesterol LDL Precipitant	D13136	5 x 100 ml
	D13137	5 x 50 ml
	D13138	5 x 25 ml
	D13139	5 x 10 ml



Addendum to the Declaration of Conformity for Devices other than those covered by Annex II (Clinical Chemistry)



Calibrators

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

Standards

	REF	CONT		REF	CONT
Albumin Standard	D95555	1 x 3 ml	Lithium Standard Set (3 levels)	910280	3 x 3 ml
Ammonia Standard	Y08310SV	1 x 5 ml	Lithium Standard Set (5 levels)	910285	5 x 3 ml
Bile Acids Standard	903210	1 x 3 ml	Magnesium Standard	D95339	1 x 3 ml
Calcium Standard	D95094	1 x 3 ml	NEFA Standard	D07963SV	1 x 3 ml
Chloride Standard	D95108	1 x 3 ml	Phosphorus Standard	D95362	1 x 3 ml
Cholesterol Standard	D95114	1 x 3 ml	Potassium Standard Set (2 levels)	910180	2 x 3 ml
CO2 Standard	D06520SV	1 x 3 ml	Protein Total Standard	D94683	1 x 3 ml
Copper Standard	507163SV	1 x 3 ml	Protein Total in Urine/CSF Standard	D03600	1 x 3 ml
Creatinine Standard	D94592	1 x 3 ml	Sodium Standard Set (2 levels)	909680	2 x 3 ml
Glucose Standard	D95223	1 x 3 ml	Triglycerides Standard	D95380	1 x 3 ml
beta-Hydroxybutyrate Standard	D10090SV	1 x 3 ml	Urea Standard	D95706	1 x 3 ml
Iron Standard	D95305	1 x 3 ml	Uric Acid Standard	D94708	1 x 3 ml
			Zinc Standard	507263SV	1 x 3 ml

Controls

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





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CE Declaration of Conformity

Manufacturer: Zhejiang SKG Medical Technology Co., Ltd.

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

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

