

No. QS5 044751 0140 Rev. 05

**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



See Page 2 for Overall Scope Statement.

ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

SH2305501

2023-07-01

2026-06-30

Date of Issue: 2023-05-25

(Renee Walker)
Director, US Certification Body, MHS

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuv-sud.com





CERTIFICATE

No. QS5 044751 0140 Rev. 05

Overall Scope Statement:

Design and Development, Production and Distribution of
 Equipment (including Patient Monitor and Accessories,
 Vital Signs Monitor, Center Monitoring System, Telemetry
 Monitoring System, Pulse Oximeter, Temperature Probe,
 Flow Sensor, Ambulatory Blood Pressure Monitor,
 Defibrillator / Monitor and Accessories,
 Electrocardiograph, Anesthesia Machine and Accessories,
 Ventilator, Air Compressor, Endoscope Camera System,
 Endoscope Light Source and Accessories, Ultrasonic
 Diagnostic Equipment and Accessories, Digital
 Radiography System, Radiography System, Hematology
 Analyzer, Clinical Chemistry Analyzer, Urine Analyzer,
 Microplate Reader, Microplate Washer for In-Vitro
 Diagnostic Use, Chemiluminescence Immunoassay
 Analyzer, Flow Cytometer, (Auto) Sample Processing
 System, Auto Slide Maker and Stainer, Glycohemoglobin
 Analyzer, Specific Protein Analyzer), Reagents for
 Hematology Analyzer, Reagents for Clinical Chemistry
 Analyzer, Chemiluminescence Immunoassay Reagents,
 Chemiluminescence Immunoassay Calibrators and
 Controls, Reagents for Flow Cytometer, Reagents for
 Glycohemoglobin Analyzer, Calibrators and Controls for
 Glycohemoglobin Analyzer, Coagulation Analyzer and
 Accessories, Coagulation Reagents, Calibrators and
 Controls for Coagulation Analyzer, Automated Digital Cell
 Morphology Analyzer, Ion-Selective Electrodes,
 Disposable Anesthesia Mask, Reusable Anesthesia Mask,
 Respiratory Mask, Disposable Breathing Circuit, Reusable
 Breathing Circuit, Heat and Moisture Exchanger, Filter,
 Breathing Bag, Tympanic Thermometer, Wireless Module,
 Wireless Device

Page 2 of 4

Date of Issue: 2023-05-25

(Renee Walker)
 Director, US Certification Body, MHS

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TUV®





CERTIFICATE

No. QS5 044751 0140 Rev. 05

Facility(ies):

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

Facility Scopes:

Design and Development, Production and Distribution of
 Equipment (including Patient Monitor and Accessories, Vital
 Signs Monitor, Center Monitoring System, Telemetry Monitoring
 System, Pulse Oximeter, Temperature Probe, Flow Sensor,
 Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and
 Accessories, Electrocardiograph, Anesthesia Machine and
 Accessories, Ventilator, Air Compressor, Endoscope Camera
 System, Endoscope Light Source and Accessories, Ultrasonic
 Diagnostic Equipment and Accessories, Digital Radiography
 System, Radiography System, Hematology Analyzer, Clinical
 Chemistry Analyzer, Urine Analyzer, Microplate Reader,
 Microplate Washer for In-Vitro Diagnostic Use,
 Chemiluminescence Immunoassay Analyzer, Flow Cytometer,
 (Auto) Sample Processing System, Auto Slide Maker and
 Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer),
 Reagents for Hematology Analyzer, Reagents for Clinical
 Chemistry Analyzer, Chemiluminescence Immunoassay
 Reagents, Chemiluminescence Immunoassay Calibrators and
 Controls, Reagents for Flow Cytometer, Reagents for
 Glycohemoglobin Analyzer, Calibrators and Controls for
 Glycohemoglobin Analyzer, Coagulation Analyzer and
 Accessories, Coagulation Reagents, Calibrators and Controls
 for Coagulation Analyzer, Automated Digital Cell Morphology
 Analyzer, Ion-Selective Electrodes, Disposable Anesthesia
 Mask, Reusable Anesthesia Mask, Respiratory Mask,
 Disposable Breathing Circuit, Reusable Breathing Circuit, Heat
 and Moisture Exchanger, Filter, Breathing Bag, Tympanic
 Thermometer, Wireless Module, Wireless Device

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Date of Issue: 2023-05-25

(Renee Walker)
 Director, US Certification Body, MHS

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America

CERTIFICATE

No. QS5 044751 0140 Rev. 05

Facility(ies):

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

Facility Scopes:

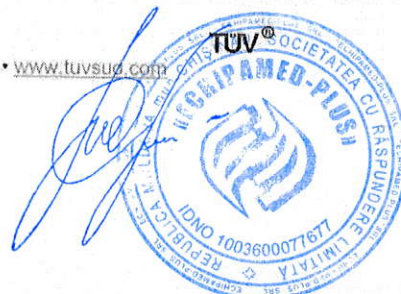
Design and Development, Production and Distribution of Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Endoscope Light Source and Accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer, Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer, Wireless Module, Wireless Device

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Date of Issue: 2023-05-25

(Renee Walker)
Director, US Certification Body, MHS

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DAkkS

Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

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

Christoph Dicks
Head of Certification/Notified Body



TUV®



DAkkS

Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 044751 0164 Rev. 05

Applied Standard(s):

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

Facility(ies):

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

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

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

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



Certificate

No. Q5 044751 0164 Rev. 05

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

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



Declaration of Conformity



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

Manufacturer SRN: CN-MF-000014156

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

Product: Chemistry Analyzer

Model: BS-600M、BS-620M

Basic UDI-DI: 69449040SHYQ-BA6M*****4T

Classification: Class A (According to Rule 5 of IVDR annex VIII)

Conformity Assessment Route: Annex II and III of IVDR

GMDN code: 56676

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

References to CS: /

Notified Body: /

Notified Body No. : /

Identification of the Certificate: /

Start of CE-Marking: 2022.3.25

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

Place, Date of Issue: Shenzhen, 2022.3.25

Signature:

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Deputy Director, Technical Regulation Department

Applied Standards List

Product: Chemistry Analyzer

Model: BS-600M、BS-620M

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-3:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 61010-1:2010/A1:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN IEC 61010-2-081:2020	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
IEC 61010-2-101:2018	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

EN 61010-2-010:2020	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN61326-1:2021	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN61326-2-6:2021	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
BS ISO 20916:2019	In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice



Declaration of Conformity

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

Manufacturer SRN: CN-MF-000014156

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

Product: The products list as attachment

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

Conformity Assessment Route: IVDD Annex III (excluding Section 6)

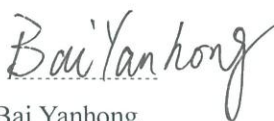
We declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

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

Place, Date of Issue: Shenzhen, 2022.4.25

Signature: 

Name of Authorized Signatory: Bai Yanhong

Position Held in Company: Manager, Technical Regulation Department

Attachment of Declaration of Conformity: Products List

Products List

NO	Product Name	catalog number
1	Magnesium Kit (Xylidyl Blue Method)	105-000834-00
2		105-000873-00
3		105-001609-00
4	Bilirubin Direct Kit (DSA Method)	105-000851-00
5		105-000890-00
6		105-001626-00
7	Bilirubin Total Kit (DSA Method)	105-000850-00
8		105-000889-00
9		105-001625-00
10	Phosphorus Kit (Phosphomolybdate Method)	105-015573-00
11		105-015574-00
12		105-015575-00
13	Total Protein Kit (Biuret Method)	105-015586-00
14		105-015587-00
15		105-015588-00
16	Phosphorus Kit (Phosphomolybdate Method)	105-000833-00
17		105-000872-00
18		105-001608-00
19	Total Protein Kit (Biuret Method)	105-000823-00
20		105-000862-00
21		105-001598-00
22	Multi Sera Calibrator	105-001127-00
23	ClinChem Multi Control (level 1)	105-009117-00
24	ClinChem Multi Control (level 2)	105-009118-00
25	TRF control	105-002318-00
26	UIBC control	105-002307-00



Declaration of Conformity

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

Manufacturer SRN: CN-MF-000014156

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

Product: See Attachment I

Catalogue Number: See Attachment I

Classification: Class A (According to Rule 5 of IVDR Annex VIII)

Conformity Assessment Route: Annex II and III of IVDR

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

References to CS: /

Notified Body: /

Notified Body No. : /

Identification of the Certificate: /

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

Place, Date of Issue: Shenzhen, 2025.6.23

Signature:

Name of Authorized Signatory:

Bai Yanhong

Position Held in Company:

Manager, Technical Regulation Department

Attachment I

NO	Product Name	Catalogue Number
1	MR Buffer Solution	105-001688-00
2	MR Buffer Solution	105-036023-00
3	MR Detergent Solution	105-001692-00
4	MR Na/K Check Solution	105-001693-00
5	CD80 Detergent	105-035958-00
6	CD80 Detergent	105-000106-00
7	CD80 Detergent	105-000748-00
8	CD80 Detergent	105-000107-00
9	CD80 Detergent	105-011705-00

Declaration of Conformity



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

Manufacturer SRN: CN-MF-000014156

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

Product: See Attachment I

Catalogue Number: See Attachment I

Classification: See Attachment I

Conformity Assessment Route: Annex IX excluding CHAPTER II

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

References to CS: /

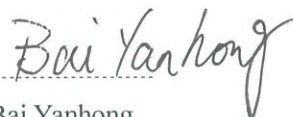
Notified Body: TÜV SÜD Product Service GmbH Ridlerstraße 65
80339 München, Germany.

Notified Body No. : 0123

Identification of the Certificate: NO. V12 044751 0190

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

Place, Date of Issue: Shenzhen, 2025.6.23

Signature: 

Name of Authorized Signatory: Bai Yanhong

Position Held in Company: Manager, Technical Regulation Department

Attachment I

NO	Product Name	catalog number	Classification
1	Lipoprotein (a) Kit (Latex Immunoturbidimetric Method)	105-019437-00	B
2		105-019439-00	
3		105-019441-00	
4	Lipoprotein (a) Calibrator	105-026280-00	B
5	Lipoprotein (a) Control	105-019443-00	B
6	Total Cholesterol Kit (CHOD-POD Method)	105-000820-00	B
7		105-000859-00	
8		105-001595-00	
9	Triglycerides Kit (GPO-POD Method)	105-000821-00	B
10		105-000860-00	
11		105-001596-00	
12	Alkaline Phosphatase Kit (IFCC Modified Method)	105-000816-00	B
13		105-000855-00	
14		105-004593-00	
15	Albumin Kit (Bromcresol Green Method)	105-000822-00	B
16		105-000861-00	
17		105-001597-00	
18	α -Amylase Kit (IFCC Method)	105-000847-00	C
19		105-000886-00	
20		105-001622-00	
21	Bilirubin Direct Kit (VOX Method)	105-000827-00	C
22		105-000866-00	
23		105-004599-00	
24	Bilirubin Total Kit (VOX Method)	105-000826-00	C
25		105-000865-00	
26		105-004598-00	
27	Hemoglobin A1c Kit (Enzymatic Assay Method)	105-002165-00	C
28		105-002166-00	
29		105-002167-00	
30		105-009338-00	
31		105-005737-00	
32		105-005738-00	
33	HbA1c Calibrator	105-003680-00	C
34	HbA1c Control P	105-002138-00	C
35	HbA1c Control N	105-002140-00	C
36	Uric Acid Kit (Uricase-Peroxidase Method)	105-000848-00	B
37		105-000887-00	
38		105-001623-00	
39	Urea Kit (Urease-GLDH, UV Method)	105-000824-00	B
40		105-000863-00	

41		105-004597-00	
42	Calcium Kit (Arsenazo III Method)	105-000825-00	B
43		105-000864-00	
44		105-001600-00	
45	C-Reactive Protein Kit (Turbidimetry Method)	105-000841-00	C
46		105-000880-00	
47		105-004605-00	
48	Rheumatoid Factor Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-002159-00	B
49		105-002177-00	
50		105-002179-00	
51		105-002161-00	
52	RF Calibrator	105-003683-00	B
53	Antistreptolysin "O" Kit (Latex Immunoturbidimetric Method)	105-009291-00	B
54		105-004630-00	
55		105-004631-00	
56		105-007673-00	
57		105-007674-00	
58		105-007675-00	
59		105-044230-00	
60		105-044231-00	
61		105-044232-00	
62	Antistreptolysin "O" Calibrator	105-004644-00	B
63	Alanine Aminotransferase Kit (IFCC Method)	105-000814-00	B
64		105-000853-00	
65		105-004591-00	
66	Aspartate Aminotransferase Kit (IFCC Method)	105-000815-00	B
67		105-000854-00	
68		105-004592-00	
69	Creatine Kinase Kit (IFCC Method)	105-004615-00	B
70		105-000869-00	
71		105-004600-00	
72	Creatine Kinase-MB Kit (IFCC Method)	105-004616-00	C
73		105-000870-00	
74		105-004601-00	
75	CK-MB Calibrator	105-001132-00	C
76	Glucose Kit (HK Method)	105-000832-00	C
77		105-000871-00	
78		105-004609-00	
79	Rheumatoid Factor Kit (Immunoturbidimetric Method)	105-004632-00	B
80		105-004633-00	
81		105-004634-00	
82	Rheumatoid Factor Calibrator	105-004645-00	B
83		105-004618-00	B

84	Immunoglobulin A Kit (Turbidimetry Method)	105-000881-00	
85		105-001617-00	
86	Immunoglobulin M Kit (Turbidimetry Method)	105-000843-00	B
87		105-000882-00	
88		105-004606-00	
89	Immunoglobulin G Kit (Turbidimetry Method)	105-004619-00	B
90		105-000883-00	
91		105-001619-00	
92	HDL-Cholesterol Kit (Direct Method)	105-000835-00	B
93		105-000874-00	
94		105-004610-00	
95	LDL-Cholesterol Kit (Direct Method)	105-000836-00	B
96		105-000875-00	
97		105-004611-00	
98	Gamma-Glutamyltransferase Kit (Szasz Method/IFCC stand)	105-000817-00	B
99		105-000856-00	
100		105-004594-00	
101	Creatinine Kit (Sarcosine Oxidase Method)	105-004614-00	B
102		105-000868-00	
103		105-004612-00	
104	Total Protein in Urine/CSF(TPUC)Kit (Pyrogallol Red-Molybdate Method)	105-009168-00	B
105		105-009169-00	
106		105-009170-00	
107	TPUC Control	105-009193-00	B
108	High Sensitivity C-reaction Protein Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-001942-00	C
109		105-001943-00	
110		105-001944-00	
111		105-002201-00	
112		105-002202-00	
113		105-002203-00	
114	HS-CRP Calibrator	105-003685-00	C
115	Lactate Dehydrogenase Kit (IFCC Method)	105-000818-00	B
116		105-000857-00	
117		105-004595-00	
118	Transferrin Kit (Immunoturbidimetric Assay Method)	105-004507-00	B
119		105-006178-00	
120		105-006177-00	
121		105-002246-00	
122		105-004508-00	
123		105-002247-00	
124	TRF Calibrator	105-002317-00	B
125	Iron (Fe) Kit (Colorimetric Assay)	105-002198-00	B
126		105-002199-00	

127		105-002200-00	
128	Carbon Dioxide (CO2) Kit (Enzymatic Method)	105-002189-00	B
129		105-002190-00	
130		105-002191-00	
131	Complement C3 Kit (Turbidimetry Method)	105-004617-00	B
132		105-000878-00	
133		105-001614-00	
134	Complement C4 Kit (Turbidimetry Method)	105-000840-00	B
135		105-000879-00	
136		105-004604-00	
137	Apolipoprotein A1 Kit (Turbidimetry Method)	105-000837-00	B
138		105-000876-00	
139		105-004602-00	
140	Apolipoprotein B Kit (Turbidimetry Method)	105-000838-00	B
141		105-000877-00	
142		105-004603-00	
143	Ferritin Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-006175-00	C
144		105-006176-00	
145		105-002244-00	
146		105-002245-00	
147		105-004505-00	
148		105-004506-00	
149	FER Calibrator	105-002311-00	C
150	Microalbumin Kit (Immunoturbidimetric Assay Method)	105-006173-00	B
151		105-002242-00	
152		105-002243-00	
153		105-006174-00	
154		105-004503-00	
155		105-004504-00	
156	MALB Calibrator	105-002315-00	B
157	MALB Control	105-002316-00	B
158	α -Hydroxybutyrate Dehydrogenase Kit (DGKC Method)	105-000819-00	B
159		105-000858-00	
160		105-004596-00	
161	Total Bile Acids Kit (Enzymatic Cycling Assay)	105-000867-00	B
162		105-001603-00	
163		105-004613-00	
164	Lipase Kit (Enzymatic Colorimetric Assay Method)	105-002171-00	B
165		105-002172-00	
166		105-002173-00	
167	Fructosamine (FUN) Kit (Colorimetric Assay)	105-002195-00	B
168		105-002196-00	
169		105-002197-00	

170	FUN Control	105-020477-00	B
171	Immunoglobulin E Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-020854-00	B
172		105-004501-00	
173		105-004502-00	
174		105-020853-00	
175		105-002240-00	
176		105-002241-00	
177	IgE Calibrator	105-002309-00	B
178	D-Dimer Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-012738-00	C
179		105-002236-00	
180		105-002237-00	
181		105-012737-00	
182		105-004497-00	
183		105-004498-00	
184	D-Dimer Calibrator	105-002300-00	C
185	D-Dimer Control	105-002301-00	C
186	Homocysteine (HCY) Kit (Enzymatic Cycling Method)	105-009174-00	B
187		105-009175-00	
188		105-009176-00	
189	HCY Control	105-009194-00	B
190	Adenosine Deaminase Kit (Enzymatic Colorimetric Method)	105-003177-00	B
191		105-003120-00	
192		105-003125-00	
193		105-026284-00	
194		105-026285-00	
195		105-026286-00	
196	ADA Calibrator	105-003687-00	B
197	ADA Control	105-020473-00	B
198	Unsaturated Iron Binding Capacity Kit (Colorimetric Method)	105-009265-00	B
199		105-004515-00	
200		105-004516-00	
201	UIBC Calibrator	105-002306-00	B
202	Retinol Binding Protein Kit (Particle- enhanced Immunoturbidimetric Assay Method)	105-009269-00	B
203		105-002250-00	
204		105-002251-00	
205		105-006182-00	
206		105-004511-00	
207		105-004512-00	
208	RBP Calibrator	105-002304-00	B
209	RBP Control	105-002305-00	B
210	Angiotensin Converting Enzyme Kit (Enzymatic Colorimetric Assay Method)	105-006179-00	B
211		105-002248-00	
212		105-002249-00	

213		105-006180-00	
214		105-004509-00	
215		105-004510-00	
216	ACE Calibrator	105-002313-00	B
217	ACE Control	105-002314-00	B
218	5'-Nucleotidase Kit (Enzymatic Colorimetric Method)	105-003176-00	B
219		105-003119-00	
220		105-003124-00	
221		105-026281-00	
222		105-026282-00	
223		105-026283-00	
224	5'-NT Calibrator	105-003688-00	B
225	5'-NT Control	105-020475-00	B
226	Glucose-6-Phosphate Dehydrogenase Kit (UV Enzymatic Method)	105-009264-00	C
227		105-002254-00	
228		105-002255-00	
229	G6PD Control	105-002308-00	C
230	β -Hydroxybutyrate Kit (Enzymatic Colorimetric Method)	105-006184-00	B
231		105-004513-00	
232		105-004514-00	
233	β -HB Calibrator	105-002319-00	B
234	β -HB Control	105-002320-00	B
235	α -L-Fucosidase Kit (CNPf Method)	105-003180-00	C
236		105-003123-00	
237		105-003128-00	
238	AFU Control	105-020474-00	C
239	Cholinesterase (CHE) Kit (DGKC Method)	105-002162-00	B
240		105-002163-00	
241		105-002164-00	
242	Cystatin C Kit (Latex Immunoturbidimetric Method)	105-004638-00	B
243		105-004639-00	
244		105-004640-00	
245	Cystatin C Calibrator	105-004647-00	B
246	Cystatin C Control	105-004651-00	B
247	Myoglobin Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-012736-00	C
248		105-002238-00	
249		105-002239-00	
250		105-012735-00	
251		105-004499-00	
252		105-004500-00	
253	MYO Calibrator	105-002302-00	C
254	Prealbumin Kit (Turbidimetry Method)	105-000845-00	B
255		105-000884-00	

256		105-004607-00	
257	Prealbumin Calibrator	105-001130-00	B
258	Glucose Kit (GOD-POD Method)	105-000849-00	C
259		105-000888-00	
260		105-001624-00	
261	β 2-Microglobulin Kit (Latex Immunoturbidimetric Method)	105-004641-00	B
262		105-004642-00	
263		105-004643-00	
264	β 2-Microglobulin Calibrator(for Serum)	105-004648-00	B
265	β 2-Microglobulin Calibrator(for Urine)	105-004649-00	B
266	β 2-Microglobulin Control	105-004652-00	B
267	Multi Sera Calibrator	105-001144-00	C
268	Specific Proteins Calibrator	105-001129-00	C
269	Lipids Calibrator	105-001128-00	B
270	Multimmun control	105-002303-00	C
273	ClinChem Multi Control (level 1)	105-009119-00	C
274	ClinChem Multi Control (level 2)	105-009120-00	C
275	ASO/CRP/RF Triple Control	105-004650-00	C
276	CO2 and TBA Multi Control	105-020476-00	B
277	MR Serum Standard	105-001689-00	B
278	MR Urine Standard	105-001690-00	B
279	MR Urine Quality Control	105-001691-00	B
280	Chloride Electrode	040-000542-00	B
281	Potassium Electrode	040-000541-00	B
282	Reference Electrode	040-000539-00	B
283	Sodium Electrode	040-000540-00	B
284	Chloride Electrode	115-084091-00	B
285	Potassium Electrode	115-084089-00	B
286	Reference Electrode	115-084088-00	B
287	Sodium Electrode	115-084090-00	B

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:2018+A11:2021. 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 D1030000083 and D1030000087).

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.: D1030000085, D1030000082, and D1030000086 respectively).

We further confirm in our sole responsibility that the IVD products listed in the attachments are designed, manufactured and controlled by us in accordance with the European Regulation 2017/746 on in vitro medical devices. Article 110 of this regulation is amended by EU Regulation 2022/112 establishing transitional periods for so called legacy products, which have already been CE-marked before May 26th, 2022 according to the European Directive 98/79. The transitional periods granted are: up to May 26th, 2025 for class D IVDs and for products covered by a certificate under 98/79/EC, up to May 26th, 2026 for class C IVDs and up to May 26th, 2027 for class B IVDs. Applicable conformity assessment procedures according to said regulations/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 that the products are either in conformity with the European Regulation 2017/746 (IVDs in attachment I) or continue to be in conformity with Directive 98/79/EC without any significant changes in the design and intended purpose (IVDS in attachment II). All IVD products also conform with the respective harmonized standards.

Human

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

HUMAN Gesellschaft für Biochemica und Diagnostica mbH

Dr. Torsten Borchers
Vice President Quality Assurance and Regulatory Affairs

Date: 2024-08-20

Cat.-no.	Product name	Class
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
11141	CRP Buffer	Others
11143	Homocysteine liquiUV Control Set	Others
11145	Homocysteine liquiUV Calibrator Set	Others
11150	Cystatin-C liquidirect	Others
11153	Cystatin-C liquidirect Controls	Others
11155	Cystatin-C liquidirectCalibrators	Others
11241	CRP	Others
11241300	CRP	Others
11241600	CRP	Others
11251300	Anti-Streptolysin-O	Others
11251600	Anti-Streptolysin-O	Others
11251P	ASO Reagent Kit	Others
11261300	Rheumatoid Factors	Others
11261600	Rheumatoid Factors	Others
11261PA	RF Reagent Kit	Others
11341	CRP Standard	Others
11351	ASO Standard	Others
11361	RF Standard	Others
11501	Immunoglobulins direct IgA direct Reagent kit	Others
11501300	Immunoglobulins direct IgA	Others
11501600	Immunoglobulins direct IgA	Others
11502	Immunoglobulins direct IgG direct Reagent kit	Others
11502300	Immunoglobulins direct IgG	Others
11502600	Immunoglobulins direct IgG	Others
11503	Immunoglobulins direct IgM direct Reagent kit	Others
11503300	Immunoglobulins direct IgM	Others
11503600	Immunoglobulins direct IgM	Others

Cat.-no.	Product name	Class
11504	Immunoglobulins direct IgG, IgA, IgM Calibrator Set	Others
11610	Ferritin Reagent Kit	Others
11610600	Ferritin	Others
11614	Ferritin Calibrator	Others
12006	Lipase liquicolor	Others
12006600	Lipase liquicolor	Others
12007	Cholinesterase liquicolor	Others
12007300	Cholinesterase liquicolor	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
12014600	LDH SCE mod. liquiUV	Others
12015	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
12021300	GOT (ASAT) IFCC mod. liquiUV	Others
12021600	GOT (ASAT) IFCC mod. liquiUV	Others
12022	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
12023300	gamma GT liquicolor	Others
12023600	gamma GT liquicolor	Others
12024	LDH liquiUV	Others
12026	Lipase liquicolor	Others
12027	Alkaline Phosphatase liquicolor	Others
12027600	Alkaline Phosphatase opt. Liquicolor	Others
12028	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(ALAT) 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
12118600	CK-MB liquiUV	Others
12127	Alkaline Phosphatase liquicolor IFCC	Others

Cat.-no.	Product name	Class
12137	Alkaline Phosphatase Iquicolor IFCC	Others
12211	GOT(ASAT) IquiuV M-Test	Others
12212	GPT(ALT) IquiuV M-Test	Others
12213	Gamma-GT Iquicolor M-Test	Others
12214	LDH IquiuV M-Test	Others
12217	Alk.Phos.Iquicolor M-Test	Others
12218	Alpha-Amylase Iquicolor M-Test	Others
12290	Iron TPTZ Iquicolor	Others
12290300	Iron TPTZ Iquicolor	Others
12290600	Iron TPTZ Iquicolor	Others
12291	Iron TPTZ Iquicolor	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	HumaSRate24 ^{PT}	Others
15024/40	HSRate Control	Others
156004	Albumin Iquicolor	Others
157004	Total Protein Iquicolor	Others
16085/50	HumaMeter A1c Reagent Kit	Others
16086	HumaMeter A1c Control Kit	Others
16185	HumaNex A1c Reagent Kit	Others
16187	HumaNex A1c Calibrator Kit	Others
16189	HumaNex A1c Control Kit	Others
16190/10	HumaNex A1c Variant Column	Others
16197	HumaNex A1c Variant Calibrator	Others
16199	HumaNex A1c Variant Control	Others
16420/30	HumaCount 30 ^{TS}	Others
16420/80	HumaCount 80 ^{TS}	Others
16430	HumaCount 5L	Others
16430/10	Automatic Sample Loader	Others
16430/50	HC5L-Control	Others
16450	HumaCount 5D	Others
16450/40	HC5D Control	Others
16451	HumaCount 5D ^{CRP}	Others
16451/40	CRP-Control HumaCount 5D ^{CRP}	Others
16451/50	CRP-Calibrator HumaCount 5D ^{CRP}	Others
16451/70	CRP-Reagent HumaCount 5D ^{CRP}	Others
17400/40	HC-Control	Others
17400/50	HC-Calibrator	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

Cat.-no.	Product name	Class
17470/70	QC Solution	Others
17470/82	Reagent Pack HumaLyte Plus ³	Others
17470/83	Reagent Pack HumaLyte Plus ⁵	Others
17470/110	QC Solution	Others
17560	HumaSens2.0 Starter Pack	II,B
17562	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 HumaSens 2.0 ^{plus}	Others
17567/10	Total Cholesterol Control Solution HumaSens 2.0 ^{plus}	Others
22132	Combina 13	Others
23111	Combina 11 S	Others
27032P	Hexagon Troponin	Others
28009	Hexagon OBTI	Others
28009/2/12	Hexagon OBTI	Others
28021/1	Hexagon OBTI	Others
28024	Hexagon OBTI	Others
28025	Hexagon OBTI	Others
28032	Hexagon PSA	II, B
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
36003	HemoStat D-Dimer	Others
36012	HemoStat D-Dimer Control high/low	Others
36102	HemoStat Antithrombin liquid	Others
36201	HemoStat free Protein S	Others
40030,	SLE Latex Test	Others
40038	IM Quick	Others
40043, 40040	Humatex CRP	Others
40053, 40050	Humatex RF	Others
40063, 40060	Humatex ASO	Others
50001, 50002, 50016	Syphilis RPR	Others

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

According to Art.17 of Regulation 2017/746 (EU) on In Vitro Diagnostic Medical Devices

ARCHEM SAĞLIK SANAYİ VE TİCARET ANONİM ŞİRKETİ

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Product Information

Product Name : CD80 DETERGENT
Brand Name : ARCHEM
Classification : Class A, according to Rule 5 of IVDR Annex VIII
Basic UDI-DI : 869901528AR00LM

Conformity Assessment: The conformity of the determined product to the In Vitro Diagnostic Medical Devices Regulation (EU)2017/746 was evaluated by issuing the EU declaration of conformity referred to in Article 17, after the technical documents specified in Annex-IV (Annex II and III) were prepared.

This declaration of conformity is the responsibility of our company.

We declare that the above-mentioned products meet the requirements of the in Vitro Diagnostic Medical Device regulation (EU) 2017/746 and the applicable standards above.

List of Directive and Standard Applied:

EN ISO 20417: 2021
EN ISO 15223-1:2016
EN ISO 18113-1:2011
EN ISO 14971:2019
EN ISO 13485:2016



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EC DECLARATION OF CONFORMITY

According to Art.17 of Regulation 2017/746 (EU) on In Vitro Diagnostic Medical Devices

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Product Information

Product Name : PROBE CLEANSER
Brand Name : ARCHEM
Classification : Class A, according to Rule 5 of IVDR Annex VIII
Basic UDI-DI : 869901528AR00LM

Conformity Assessment: The conformity of the determined product to the In Vitro Diagnostic Medical Devices Regulation (EU)2017/746 was evaluated by issuing the EU declaration of conformity referred to in Article 17, after the technical documents specified in Annex-IV (Annex II and III) were prepared.

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CONFORMITY DECLARATION CE

With a full responsibility, we declare that products:

water purification systems (demineralizers) – models: **HLP SMART, HLP 5, HLP 5S, HLP 5P, HLP 5SP, HLP 5UV, HLP 10, HLP 10S, HLP 10P, HLP 10SP, HLP 10UV, HLP 20P, HLP 20S, HLP 20SP, HLP 20UV, HLP 30P, HLP 30S, HLP 30SP, HLP 30UV, HLP 40**

fit the requirements of directives listed below:

- low-voltage electric device (LVD) No 2014/35/EU
- electromagnetic compatibility (EMC) No 2014/30/EU
- on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS II) 2011/65 / EU

Evaluation was performed by using harmonized standards:

- PN-EN 61010 Wymagania bezpieczeństwa dotyczące elektrycznych przyrządów do pomiarów, sterowania i użytku z laboratoriach.
- PN-EN 61326 Wyposażenie elektryczne do pomiarów, sterowania i użytku w laboratoriach. Wymagania dotyczące kompatybilności elektromagnetycznej (EMC),
- PN-EN 62311 Ocena sprzętu elektronicznego i elektrycznego związana z ograniczeniami narażania ludzi na działanie pól elektromagnetycznych (0 Hz - 300 GHz)
- PN-EN 50581 Dokumentacja techniczna oceny wyrobów elektrycznych i elektronicznych z uwzględnieniem ograniczenia stosowania substancji niebezpiecznych

Last two digits of the year, when the CE was issued: 14.

Przemysław Ganczarek

Date: 02/01/2021

Przemysław Ganczarek

