

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

Date: 07.02.2025

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, 2025**. 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,


Gao Xiufu


Regional Sales & Marketing Manager, IVD Sales & Marketing Department, Central Asia
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 81888998
Fax: +86 755 26582680
Website: www.mindray.com



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

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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

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Date of Issue: 2023-05-25

(Renee Walker)
 Director, US Certification Body, MHS

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TUV®





America

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:

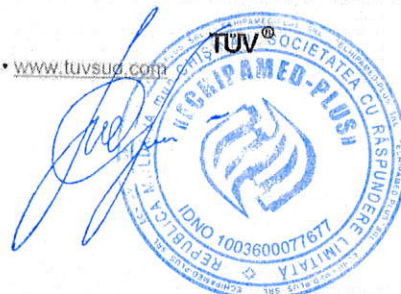
Design and Development, Production and Distribution of Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, 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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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



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-430、BS-450、BS-460、BS-410、BS-410E、BS-410S、
BS-470、BS-470E

Basic UDI-DI: 69449040SHYQ-BA43*****N9

Intended Purpose: The system is an chemistry analyzer for in vitro diagnostic use in
clinical laboratories and designed for in vitro quantitative
determination of clinical chemistries in serum, plasma, urine or
cerebrospinal fluid samples.

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: 2022.4.25

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, 2022.4.25

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-430、BS-450、BS-460、BS-410、BS-410E、BS-410S、BS-470、BS-470E

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 15223-1:2016	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
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2013	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 –V1.0

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

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

Product: Chemistry Analyzer

Model: BS-430、BS-450、BS-460、BS-410、BS-410E、BS-410S、
BS-470、BS-470E

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 2011/65/EU. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

EN IEC 63000: 2018 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Start of CE-Marking: 2022.4.25

Place, Date of Issue: Shenzhen. 2022.4.25

Signature:



Name of Authorized Signatory: Mr.WangXinBing

Position Held in Company: Deputy Director, Technical Regulation Department

Declaration of Conformity



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

Manufacturer SRN: CN-MF-000014156

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

Product: See Attachment I

Catalogue Number: See Attachment I

Classification: See Attachment I

Conformity Assessment Route: Annex IX excluding CHAPTER II

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

References to CS: /

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

Notified Body No. : 0123

Identification of the Certificate: NO. V12 044751 0190

Start of CE-Marking: 2022.8.25

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

Place, Date of Issue: Shenzhen, 2024.12.11

Signature:

Name of Authorized Signatory:

Position Held in Company:



Bobby Liu

Manager, Technical Regulation Department



Attachment I

NO	Product Name	Catalogue Number	Classification
1	Lipoprotein (a) Kit (Latex Immunoturbidimetric Method)	105-019437-00	Class B (According to Rule 6 of IVDR Annex VIII)
2		105-019439-00	
3		105-019441-00	
4	Lipoprotein (a) Control	105-019443-00	Class B (According to Rule 6 of IVDR Annex VIII)
5	Total Cholesterol Kit (CHOD-POD Method)	105-000820-00	Class B (According to Rule 6 of IVDR Annex VIII)
6		105-000859-00	
7		105-001595-00	
8	Triglycerides Kit (GPO-POD Method)	105-000821-00	Class B (According to Rule 6 of IVDR Annex VIII)
9		105-000860-00	
10		105-001596-00	
11	Alkaline Phosphatase Kit (IFCC Modified Method)	105-000816-00	Class B (According to Rule 6 of IVDR Annex VIII)
12		105-000855-00	
13		105-004593-00	
14	Albumin Kit (Bromocresol Green Method)	105-000822-00	Class B (According to Rule 6 of IVDR Annex VIII)
15		105-000861-00	
16		105-001597-00	
17	α -Amylase Kit (IFCC Method)	105-000847-00	Class C (According to Rule 3 of IVDR Annex VIII)
18		105-000886-00	
19	Bilirubin Direct Kit (VOX Method)	105-000827-00	Class C (According to Rule 3 of IVDR Annex VIII)
20		105-000866-00	
21		105-004599-00	
22	Bilirubin Total Kit (VOX Method)	105-000826-00	Class C (According to Rule 3 of IVDR Annex VIII)
23		105-000865-00	
24		105-004598-00	
25	HbA1c Calibrator	105-003680-00	Class C (According to Rule 3 of IVDR Annex VIII)
26	HbA1c Control P	105-002138-00	Class C (According to Rule 3 of IVDR Annex VIII)
27	HbA1c Control N	105-002140-00	Class C (According to Rule 3 of IVDR Annex VIII)
28	Uric Acid Kit (Uricase-Peroxidase Method)	105-000887-00	Class B (According to Rule 6 of IVDR Annex VIII)

29	Urea Kit (Urease-GLDH, UV Method)	105-000824-00	Class B (According to Rule 6 of IVDR Annex VIII)
30		105-000863-00	
31		105-004597-00	
32	Phosphorus Kit (Phosphomolybdate Method)	105-000833-00	Class B (According to Rule 6 of IVDR Annex VIII)
33		105-000872-00	
34		105-001608-00	
35	Calcium Kit (Arsenazo III Method)	105-000825-00	Class B (According to Rule 6 of IVDR Annex VIII)
36		105-000864-00	
37		105-001600-00	
38	C-Reactive Protein Kit (Turbidimetry Method)	105-000841-00	Class C (According to Rule 3 of IVDR Annex VIII)
39		105-000880-00	
40		105-004605-00	
41	Rheumatoid Factor Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-002179-00	Class B (According to Rule 6 of IVDR Annex VIII)
42		105-002161-00	
43	RF Calibrator	105-003683-00	Class B (According to Rule 6 of IVDR Annex VIII)
44	Antistreptolysin "O" Kit (Latex Immunoturbidimetric Method)	105-009291-00	Class B (According to Rule 6 of IVDR Annex VIII)
45		105-004630-00	
46		105-004631-00	
47		105-007673-00	
48		105-007674-00	
49		105-007675-00	
50	Antistreptolysin "O" Calibrator	105-004644-00	Class B (According to Rule 6 of IVDR Annex VIII)
51	Alanine Aminotransferase Kit (IFCC Method)	105-000814-00	Class B (According to Rule 6 of IVDR Annex VIII)
52		105-000853-00	
53		105-004591-00	
54	Aspartate Aminotransferase Kit (IFCC Method)	105-000815-00	Class B (According to Rule 6 of IVDR Annex VIII)
55		105-000854-00	
56		105-004592-00	
57	Creatine Kinase Kit (IFCC Method)	105-004615-00	Class B (According to Rule 6 of IVDR Annex VIII)
58		105-000869-00	
59		105-004600-00	
60	Creatine Kinase-MB Kit (IFCC Method)	105-004616-00	Class C (According to Rule 3 of IVDR Annex VIII)
61		105-000870-00	
62		105-004601-00	
63	CK-MB Calibrator	105-001132-00	Class C (According to Rule 3 of IVDR Annex VIII)

64	Glucose Kit (HK Method)	105-000832-00	Class C (According to Rule 3 of IVDR Annex VIII)
65		105-000871-00	
66		105-004609-00	
67	Rheumatoid Factor Kit (Immunoturbidimetric Method)	105-004632-00	Class B (According to Rule 6 of IVDR Annex VIII)
68		105-004633-00	
69		105-004634-00	
70	Rheumatoid Factor Calibrator	105-004645-00	Class B (According to Rule 6 of IVDR Annex VIII)
71	Immunoglobulin A Kit (Turbidimetry Method)	105-004618-00	Class B (According to Rule 6 of IVDR Annex VIII)
72		105-000881-00	
73		105-001617-00	
74	Immunoglobulin M Kit (Turbidimetry Method)	105-000843-00	Class B (According to Rule 6 of IVDR Annex VIII)
75		105-000882-00	
76		105-004606-00	
77	Immunoglobulin G Kit (Turbidimetry Method)	105-004619-00	Class B (According to Rule 6 of IVDR Annex VIII)
78		105-000883-00	
79		105-001619-00	
80	HDL-Cholesterol Kit (Direct Method)	105-000835-00	Class B (According to Rule 6 of IVDR Annex VIII)
81		105-000874-00	
82		105-004610-00	
83	LDL-Cholesterol Kit(Direct Method)	105-000836-00	Class B (According to Rule 6 of IVDR Annex VIII)
84		105-000875-00	
85		105-004611-00	
86	Gamma-Glutamyltransferase Kit (Szasz Method/IFCC stand)	105-000817-00	Class B (According to Rule 6 of IVDR Annex VIII)
87		105-000856-00	
88		105-004594-00	
89	Creatinine Kit (Sarcosine Oxidase Method)	105-004614-00	Class B (According to Rule 6 of IVDR Annex VIII)
90		105-000868-00	
91		105-004612-00	
92	Total Protein Kit (Biuret Method)	105-000823-00	Class B (According to Rule 6 of IVDR Annex VIII)
93	Total Protein in Urine/CSF(TPUC)Kit (Pyrogallol Red-Molybdate Method)	105-009168-00	Class B (According to Rule 6 of IVDR Annex VIII)
94		105-009169-00	
95		105-009170-00	
96	TPUC Control	105-009193-00	Class B (According to Rule 6 of IVDR Annex VIII)
97	High Sensitivity C-reaction Protein Kit (Particle-enhanced)	105-001942-00	Class C (According to Rule 3 of IVDR Annex VIII)
98		105-001943-00	
99		105-001944-00	

	Immunoturbidimetric Assay Method)		
100	HS-CRP Calibrator	105-003685-00	Class C (According to Rule 3 of IVDR Annex VIII)
101	Urea Kit (Urease-GLDH, UV Method)	105-000818-00	Class B (According to Rule 6 of IVDR Annex VIII)
102		105-000857-00	
103		105-004595-00	
104	Transferrin Kit (Immunoturbidimetric Assay Method)	105-004507-00	Class B (According to Rule 6 of IVDR Annex VIII)
105		105-006178-00	
106		105-006177-00	
107		105-002246-00	
108		105-004508-00	
109		105-002247-00	
110	TRF Calibrator	105-002317-00	Class B (According to Rule 6 of IVDR Annex VIII)
111	Iron (Fe) Kit (Colorimetric Assay)	105-002198-00	Class B (According to Rule 6 of IVDR Annex VIII)
112		105-002199-00	
113	Carbon Dioxide (CO2) Kit (Enzymatic Method)	105-002190-00	Class B (According to Rule 6 of IVDR Annex VIII)
114		105-002191-00	
115	Complement C3 Kit (Turbidimetry Method)	105-004617-00	Class B (According to Rule 6 of IVDR Annex VIII)
116		105-000878-00	
117		105-001614-00	
118	Complement C4 Kit (Turbidimetry Method)	105-000840-00	Class B (According to Rule 6 of IVDR Annex VIII)
119		105-000879-00	
120		105-004604-00	
121	Apolipoprotein A1 Kit (Turbidimetry Method)	105-000837-00	Class B (According to Rule 6 of IVDR Annex VIII)
122		105-000876-00	
123		105-004602-00	
124	Apolipoprotein B Kit (Turbidimetry Method)	105-000838-00	Class B (According to Rule 6 of IVDR Annex VIII)
125		105-000877-00	
126		105-004603-00	
127	Ferritin Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-006175-00	Class C (According to Rule 3 of IVDR Annex VIII)
128		105-006176-00	
129		105-002244-00	
130		105-002245-00	
131		105-004505-00	
132		105-004506-00	

133	FER Calibrator	105-002311-00	Class C (According to Rule 3 of IVDR Annex VIII)
134	Microalbumin Kit (Immunoturbidimetric Assay Method)	105-006173-00	Class B (According to Rule 6 of IVDR Annex VIII)
135		105-002242-00	
136		105-002243-00	
137		105-006174-00	
138		105-004503-00	
139		105-004504-00	
140	MALB Calibrator	105-002315-00	Class B (According to Rule 6 of IVDR Annex VIII)
141	MALB Control	105-002316-00	Class B (According to Rule 6 of IVDR Annex VIII)
142	α -Hydroxybutyrate Dehydrogenase Kit (DGKC Method)	105-000819-00	Class B (According to Rule 6 of IVDR Annex VIII)
143		105-000858-00	
144		105-004596-00	
145	Total Bile Acids Kit (Enzymatic Cycling Assay)	105-000867-00	Class B (According to Rule 6 of IVDR Annex VIII)
146		105-001603-00	
147		105-004613-00	
148	Lipase Kit (Enzymatic Colorimetric Assay Method)	105-002171-00	Class B (According to Rule 6 of IVDR Annex VIII)
149		105-002172-00	
150		105-002173-00	
151	Fructosamine (FUN) Kit (Colorimetric Assay)	105-002195-00	Class B (According to Rule 6 of IVDR Annex VIII)
152		105-002196-00	
153	FUN Control	105-020477-00	Class B (According to Rule 6 of IVDR Annex VIII)
154	Immunoglobulin E Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-020854-00	Class B (According to Rule 6 of IVDR Annex VIII)
155		105-004501-00	
156		105-004502-00	
157		105-020853-00	
158		105-002240-00	
159		105-002241-00	
160	IgE Calibrator	105-002309-00	Class B (According to Rule 6 of IVDR Annex VIII)
161	D-Dimer Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-012738-00	Class C (According to Rule 3 of IVDR Annex VIII)
162		105-002236-00	
163		105-002237-00	
164		105-012737-00	

165		105-004497-00	
166		105-004498-00	
167	D-Dimer Calibrator	105-002300-00	Class C (According to Rule 3 of IVDR Annex VIII)
168	D-Dimer Control	105-002301-00	Class C (According to Rule 3 of IVDR Annex VIII)
169	Homocysteine (HCY) Kit (Enzymatic Cycling Method)	105-009174-00	Class B (According to Rule 6 of IVDR Annex VIII)
170		105-009175-00	
171		105-009176-00	
172	HCY Control	105-009194-00	Class B (According to Rule 6 of IVDR Annex VIII)
173	Adenosine Deaminase Kit (Enzymatic Colorimetric Method)	105-003177-00	Class B (According to Rule 6 of IVDR Annex VIII)
174		105-003120-00	
175		105-003125-00	
176		105-026284-00	
177		105-026285-00	
178		105-026286-00	
179	ADA Calibrator	105-003687-00	Class B (According to Rule 6 of IVDR Annex VIII)
180	ADA Control	105-020473-00	Class B (According to Rule 6 of IVDR Annex VIII)
181	Unsaturated Iron Binding Capacity Kit (Colorimetric Method)	105-009265-00	Class B (According to Rule 6 of IVDR Annex VIII)
182		105-004515-00	
183		105-004516-00	
184	UIBC Calibrator	105-002306-00	Class B (According to Rule 6 of IVDR Annex VIII)
185	Retinol Binding Protein Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-009269-00	Class B (According to Rule 6 of IVDR Annex VIII)
186		105-002250-00	
187		105-002251-00	
188		105-006182-00	
189		105-004511-00	
190		105-004512-00	
191	RBP Calibrator	105-002304-00	Class B (According to Rule 6 of IVDR Annex VIII)

192	RBP Control	105-002305-00	Class B (According to Rule 6 of IVDR Annex VIII)
193	Angiotensin Converting Enzyme Kit (Enzymatic Colorimetric Assay Method)	105-006179-00	Class B (According to Rule 6 of IVDR Annex VIII)
194		105-002248-00	
195		105-002249-00	
196		105-006180-00	
197		105-004509-00	
198		105-004510-00	
199	ACE Calibrator	105-002313-00	Class B (According to Rule 6 of IVDR Annex VIII)
200	ACE Control	105-002314-00	Class B (According to Rule 6 of IVDR Annex VIII)
201	5'-Nucleotidase Kit (Enzymatic Colorimetric Method)	105-003119-00	Class B (According to Rule 6 of IVDR Annex VIII)
202		105-003124-00	
203		105-026281-00	
204		105-026282-00	
205		105-026283-00	
206	5'-NT Calibrator	105-003688-00	Class B (According to Rule 6 of IVDR Annex VIII)
207	5'-NT Control	105-020475-00	Class B (According to Rule 6 of IVDR Annex VIII)
208	Glucose-6-Phosphate Dehydrogenase Kit (UV Enzymatic Method)	105-009264-00	Class C (According to Rule 3 of IVDR Annex VIII)
209		105-002254-00	
210		105-002255-00	
211	G6PD Control	105-002308-00	Class C (According to Rule 3 of IVDR Annex VIII)
212	β -Hydroxybutyrate Kit (Enzymatic Colorimetric Method)	105-006184-00	Class B (According to Rule 6 of IVDR Annex VIII)
213		105-004513-00	
214		105-004514-00	
215	β -HB Calibrator	105-002319-00	Class B (According to Rule 6 of IVDR Annex VIII)
216	β -HB Control	105-002320-00	Class B (According to Rule 6 of IVDR Annex VIII)
217		105-003123-00	

218	α -L-Fucosidase Kit (CNPF Method)	105-003128-00	Class C (According to Rule 3 of IVDR Annex VIII)
219	AFU Control	105-020474-00	Class C (According to Rule 3 of IVDR Annex VIII)
220	Cholinesterase (CHE) Kit (DGKC Method)	105-002162-00	Class B (According to Rule 6 of IVDR Annex VIII)
221		105-002163-00	
222	Cystatin C Kit (Latex Immunoturbidimetric Method)	105-004638-00	Class B (According to Rule 6 of IVDR Annex VIII)
223		105-004639-00	
224		105-004640-00	
225	Cystatin C Calibrator	105-004647-00	Class B (According to Rule 6 of IVDR Annex VIII)
226	Cystatin C Control	105-004651-00	Class B (According to Rule 6 of IVDR Annex VIII)
227	Myoglobin Kit (Particle-enhanced Immunoturbidimetric Assay Method)	105-012736-00	Class C (According to Rule 3 of IVDR Annex VIII)
228		105-002238-00	
229		105-002239-00	
230		105-012735-00	
231		105-004499-00	
232		105-004500-00	
233	MYO Calibrator	105-002302-00	Class C (According to Rule 3 of IVDR Annex VIII)
234	Prealbumin Kit (Turbidimetry Method)	105-000845-00	Class B (According to Rule 6 of IVDR Annex VIII)
235		105-000884-00	
236		105-004607-00	
237	Prealbumin Calibrator	105-001130-00	Class B (According to Rule 6 of IVDR Annex VIII)
238	Glucose Kit (GOD-POD Method)	105-000888-00	Class C (According to Rule 3 of IVDR Annex VIII)
239	β 2-Microglobulin Kit (Latex Immunoturbidimetric Method)	105-004641-00	Class B (According to Rule 6 of IVDR Annex VIII)
240		105-004642-00	
241		105-004643-00	
242	β 2-Microglobulin Calibrator(for Serum)	105-004648-00	Class B (According to Rule 6 of IVDR Annex VIII)

243	β 2-Microglobulin Calibrator(for Urine)	105-004649-00	Class B (According to Rule 6 of IVDR Annex VIII)
244	β 2-Microglobulin Control	105-004652-00	Class B (According to Rule 6 of IVDR Annex VIII)
245	Multi Sera Calibrator	105-001144-00	Class C (According to Rule 3 of IVDR Annex VIII)
246	Specific Proteins Calibrator	105-001129-00	Class C (According to Rule 3 of IVDR Annex VIII)
247	Lipids Calibrator	105-001128-00	Class B (According to Rule 6 of IVDR Annex VIII)
248	Multimmun control	105-002303-00	Class C (According to Rule 3 of IVDR Annex VIII)
249	ClinChem Multi Control (level 1)	105-009119-00	Class C (According to Rule 3 of IVDR Annex VIII)
250	ClinChem Multi Control (level 2)	105-009120-00	Class C (According to Rule 3 of IVDR Annex VIII)
251	ASO/CRP/RF Triple Control	105-004650-00	Class C (According to Rule 3 of IVDR Annex VIII)
252	CO2 and TBA Multi Control	105-020476-00	Class B (According to Rule 6 of IVDR Annex VIII)
253	Hemoglobin A1c Kit (Enzymatic Assay Method)	105-009338-00	Class C (According to Rule 3 of IVDR Annex VIII)
254		105-002167-00	
255		105-005738-00	

Declaration of Conformity



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
A06631H	Ceruloplasmin 5+1	2x 25 mL Buffer + 1x 10 mL Antibody Reagent
A06871H	Ceruloplasmin 5+1	5x 20 mL Buffer + 1x 20 mL Antibody Reagent
AA1012	Ceruloplasmin 5+1	1x 50 mL Buffer + 1x 12.5 mL Antibody Reagent
AT1312	Ceruloplasmin 5+1	1x 50 mL Buffer + 1x 12.5 mL Antibody Reagent
A0731911H	Ceruloplasmin 5+1	2x 50 mL Buffer + 1x 20 mL Antibody Reagent
020013	Ceruloplasmin 5+1	2x 50 mL Buffer + 1x 20 mL Antibody Reagent

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, Article 110(3) of regulation 2017/746 (IVDR) 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, Artikel 110(3) der Verordnung 2017/746 (IVDR) und des Österreichischen Medizinproduktegesetzes erfüllt.

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



Produktion und Vertrieb von chemisch-technischen
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Wiener Neudorf, 2024-12-10

Almira Dugic
Qualitätsmanagementbeauftragte
Quality Management Representative

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
A00590	Protein Control	1x 1ml
A00800		1x 5ml

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, Article 110(3) of regulation 2017/746 (IVDR) 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, Artikel 110(3) der Verordnung 2017/746 (IVDR) und des Österreichischen Medizinproduktegesetzes erfüllt.

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

Produktion und Vertrieb von chemisch - technischen
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Wiener Neudorf, 2025-02-28

Almira Dugic
Qualitätsmanagementbeauftragte
Quality Management Representative

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
A00704	Protein Calibrator 5 Level Series	5x 1 mL

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, Article 110(3) of regulation 2017/746 (IVDR) 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, Artikel 110(3) der Verordnung 2017/746 (IVDR) und des Österreichischen Medizinproduktegesetzes erfüllt.

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Produkten und Laborinstrumenten Gesellschaft m.b.H.
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Wiener Neudorf, 2025-02-28

Almira Dugic
Qualitätsmanagementbeauftragte
Quality Management Representative

EC DECLARATION OF CONFORMITY
EG-KONFORMITÄTSERKLÄRUNG



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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
A08591	Protein Control Low	1x 1ml
A08823		1x 5ml

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, Article 110(3) of regulation 2017/746 (IVDR) 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, Artikel 110(3) der Verordnung 2017/746 (IVDR) und des Österreichischen Medizinproduktegesetzes erfüllt.

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

Produktion und Vertrieb von chemisch - technischen
Produkten und Laborinstrumenten Gesellschaft m.b.H.
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Wiener Neudorf, 2025-02-28

Almira Dugic
Qualitätsmanagementbeauftragte
Quality Management Representative



Zhejiang SKG Medical Technology Co., Ltd

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

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

CE Declaration of Conformity

Manufacturer: Zhejiang SKG Medical Technology Co., Ltd.

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

PEOPLE'S REPUBLIC OF CHINA

European

Representative: Shanghai International Holding corp. GmbH(Europe)

Eiffestrasse 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

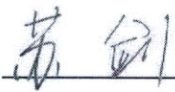
Identification number: Not applicable

(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

