Digitally signed by Iurchevici Valeriu
Date: 2026.03.20 10:29:45 EET
Reason: MoldSign Signature
Location: Moldova

CA-REGZ202601250001 MOLDOVA EUROPEANĂ

mindray

"Echipamed-Plus" SRL
str. Valea Trandafirilor, 24B, of. 2-7
MD-2001, Chisinau, Moldova
+373 22 234-349
Date: 25.01.2026

LETTER OF AUTHORIZATION

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, (**"Mindray"**) manufacturer of **biochemical, immunological and coagulation analyzers, reagents and consumables** (**"Product(s)"**), hereby certify that **"Echipamed-Plus" SRL,** with business office at **str. Valea Trandafirilor, 24B, of. 2-7, MD-2001, Chisinau, Republic of Moldova ("You")** is our official distributor and local representative for registration, sales and service of the Product(s) in **Republic of Moldova ("Territory").**

As the manufacturer, Mindray guarantees the Product(s) against defects in materials and workmanship, and provide services based on the standard terms and conditions of Mindray's warranty policy.

This authorization of distribution rights is valid from the date of issuance to **December 31, 2026.** Mindray reserves the right to terminate the authorization upon fifteen (15) days written notice without any compensation to You.

Neither this Letter of Authorization nor any further extension, will impose any obligation or grant any rights regarding further distribution of the Product(s), nor allow any party to seek compensation for goodwill developed during the term of Letter of Authorization or any further extension.

Best regards,

Yang Hang
General Manager of Sales and Marketing Division, Central Asia Region III
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Date: 25.01.2026

SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.
Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan,
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HUMAN Gesellschaft für
Biochemica und Diagnostica mbH

Max-Planck-Ring 21
65205 Wiesbaden · Germany

Telefon +49 6122 9988-0
Telefax +49 6122 9988-100

AUTHORIZATION LETTER

We, **HUMAN Gesellschaft für Biochemica und Diagnostica mbH (hereinafter called "HUMAN"),** Max - Planck - Ring 21, 65205 Wiesbaden, Germany, hereby certify that company

"Echipamed Plus" SRL
Valea Trandafirilor 24 <B>,
2001 Chisinau
Moldova

is our exclusive representative for HUMAN / IMTEC products in the territory of Moldova.

Echipamed Plus is therefore authorized to import, stock, market and sell HUMAN labeled products throughout the territory of Moldova.

Echipamed Plus is also fully authorized to participate in official tenders and to provide installation, warranty service and maintenance for HUMAN equipment in the territory of Moldova.

Echipamed Plus is further authorized to submit applications on our behalf to the competent authority of Moldova for the registration and re-registration of HUMAN-labeled products in the name of HUMAN.

This Authorization Letter remains valid until 31.12.2026 and is only effective in connection with a valid Distribution Agreement.

Wiesbaden, 23 December 2025

HUMAN Gesellschaft für Biochemica und Diagnostica mbH

André Jendretzki
International Sales Manager

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

For electronic distribution only
Nur zur elektronischen Verbreitung

Certificate

We hereby certify the company

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

with the sites listed in the attachment the introduction and application of a

Quality management system according to EN ISO 9001

in the scope

development, manufacturing and distribution of in vitro diagnostic devices and associated analyzers as well as laboratory devices and distribution of pipettes

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 9001:2015 - ISO 9001:2015
Quality management systems – Requirements

Valid from 2025-03-12
Valid until 2028-03-11

Registration No. D1030000090
Report No. P23-01546-284931

Stuttgart, 2025-03-10

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16002-01-01

For electronic distribution only
Nur zur elektronischen Verbreitung

Certificate

We hereby certify the company

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

with the sites listed in the attachment the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

development, manufacturing and distribution of reagents, reagent products, calibrators and control materials for clinical chemistry, haematology, haemostasis, immune chemistry as well as analyzers for in-vitro diagnosis and the distribution of test kits for molecular biology analyses as well as rapid tests for the diagnosis of infectious diseases

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from 2025-03-12
Valid until 2028-03-11

Registration No. D1030000091
Report No. P23-01546-284935

Stuttgart, 2025-03-10

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

Declaration of Conformity

CE

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

Date: 2024-08-20

HUMAN Gesellschaft für Biochemica und Diagnostica mbH

Dr. Torsten Börchers
Vice President Quality Assurance and Regulatory Affairs

Attachment I - List of products which passed applicable conformity assessment procedures (article 48 of European Regulation 2017/746) by date of signing

Cat.-no.	Product name	IVDR-Class	Basic UDI
11505	IMMUNOGLOBULINS direct Buffer	A	04033145CC11505CS
15500 / 15500/110	HuMax HCT	A	04033145LQ15500PT
15650	HumaClot Duo Plus	A	04033145CO15650JU
15660	HumaClot Quattro	A	04033145CO15660JX
15800	HumaClot Pro	A	04033145CO15800JP
15800/20	HumaClot Pro Wash Solution	A	04033145CO15800/20MA
15800/30	HumaClot Pro Cleaner	A	04033145CO15800/30MD
15910	HumaCLIA 150	A	04033145CL15910HQ
16080	HumaMeter A1c	A	04033145HG16080HT
16190	HumaNex A1c Variant	A	04033145HP16190MQ
16195	HumaNex A1c Variant Reagent	A	04033145HP16195N2
16300	Elisys Quattro	A	04033145EL16300HY
16430/20	HC5L-Diluent	A	04033145HC16430/20H5
16430/30	HC5L-Lyse	A	04033145HC16430/30H8
16430/40	HC5L-Diff	A	04033145HC16430/40H8
16450/10	HC5D-Diluent	A	04033145HC16450/10HQ
16450/20	HC5D-CBC-Lyse	A	04033145HC16450/20HT
16450/30	HC5D-Diff-Lyse	A	04033145HC16450/30HW
16450/60	HC5D Clean	A	04033145HC16450/60J7
16660	HumaStar 600	A	04033145CC16660EA
16661/01	Chimney	A	04033145CC16661/01EJ
16663/10	Diluent	A	04033145CC16663/10EZ
16663/11	Diluent-2	A	04033145CC16663/11F3
16663/20	Cuvette Clean	A	04033145CC18973FG
16663/25	Tip Cleaning Kit	A	04033145CC16663/25FE
16670	HumaReader HS	A	04033145EL16670K4
16700	HumaLyzer 3000	A	04033145CC16700DV
16890	HumaStar 100	A	04033145CC16890EV
16895	HumaStar 200	A	04033145CC16895F7
16930	HumaStar 300 SR	A	04033145CC16930EG
17200	Elisys Duo	A	04033145EL17200J2
17350	Elisys Uno	A	04033145EL17350JN
17400/11	HC-Diluent	A	04033145HC17400/11GL
17400/22	HC-Lyse CF	A	04033145HC17400/22GR
17400/31	HC-Cleaner	A	04033145HC17400/31GS
17400/55	HC-Regular	A	04033145HC17400/55H8
17400/56	HC-Acute	A	04033145HC17400/56HA
17470/10	HumaLyte Plus^3	A	04033145CC17470/10EE
17470/20	HumaLyte Plus^5	A	04033145CC17470/20EH

Cat.-no.	Product name	IVDR-Class	Basic UDI
17470/71	Daily Cleaning Solution	A	04033145CC17470/71F2
17470/72	Weekly Cleaning Solution	A	04033145CC17470/72F4
17470/74	K Filling Solution	A	04033145CC17470/74F8
17470/75	pH / Na / Cl Filling Solution	A	04033145CC17470/75FA
17470/76	Ca Filling Solution	A	04033145CC17470/76FC
17470/78	Reference Filling Solution	A	04033145CC17470/78FG
17470/79	Na Conditioner	A	04033145CC17470/79FJ
17470/86	Urine Diluent	A	04033145CC17470/86FF
17561	HumaSens2.0^{plus} Starter Pack	A	04033145MM17561PS
17600	Combilyzer^{13}	A	04033145US17600VZ
18000	HumaReader Single Plus	A	04033145EL18000HX
18200	HumaLyzer Primus	A	04033145CC18200DJ
18222	Flow Cell Cleaner	A	04033145CC18222DU
18250	HumaLyzer 4000	A	04033145CC18250DZ
18460	CombiWash	A	04033145EL18460K5
18680	HumaClot Junior	A	04033145CO18680KS
18971	Wash Additive	A	04033145CC18971FC
18973	Cuvette Clean	A	04033145CC18973FG
18974	Special Wash Solution	A	04033145CC18974FJ
18974/2	Special Wash Solution-2	A	04033145CC18974/2E7
19130A	AutoHumaPette 20-200µl	A	04033145LQ19130AQY
40037	GLYCINE-NaCl Buffer	A	04033145RT40037U4
80050	Pre-Trigger Solution HumaCLIA SR	A	04033145CL80050HZ
80055	Trigger Solution HumaCLIA SR	A	04033145CL80055JB
80060	Wash Buffer HumaCLIA SR	A	04033145CL80060J4
80110	Sample Diluent B HumaCLIA SR	A	04033145CL80110HS
961000	HumaLoop T	A	04033145LO961000QN
962000	HumaLoop M	A	04033145LO962000QV
963100	HumaTurb A	A	04033145LO963100R9
963200	HumaTurb C+A	A	04033145LO963100R9
ITC80000	HumaBlot 44^{FA}	A	04033145LAITC80000PU

Attachment II – List of products which passed applicable conformity assessment procedures (annex III, annex IV of European Directive 98/79) by date of signing and benefit from the transition periods granted by regulation 2022/112

Cat.-no.	Product name	Class
10010	Magnesium liquicolor	Others
10010300	Magnesium liquicolor	Others
10010600	Magnesium liquicolor	Others
10011	Calcium liquicolor	Others
10011300	Calcium liquicolor	Others
10011600	Calcium liquicolor	Others
10012	Bilirubin liquicolor	Others
10017	Cholesterol liquicolor	Others
10019	Cholesterol liquicolor	Others
10027	Phosphorus liquirapid	Others
10027300	Phosphorus liquirapid	Others
10027600	Phosphorus liquirapid	Others
10028	Cholesterol liquicolor	Others
10028300	Cholesterol liquicolor	Others
10028600	Cholesterol liquicolor	Others
10051	Creatinine liquicolor	Others
10052	auto-Creatinine liquicolor	Others
10052300	auto-Creatinine liquicolor	Others
10052600	auto-Creatinine liquicolor	Others
10053	Creatinine (Enzym) liquicolor	Others
10053300	Creatinine (Enzym) liquicolor	Others
10053600	Creatinine (Enzym) liquicolor	Others
10084	HDL Cholesterol liquicolor	Others
10084300	HDL Cholesterol liquicolor	Others
10084600	HDL Cholesterol liquicolor	Others
10094	LDL Cholesterol liquicolor	Others
10094600	LDL Cholesterol liquicolor	Others
10113	Sodium liquicolor	Others
10113300	Sodium liquicolor	Others
10113600	Sodium liquicolor	Others
10114	Sodium Standard	Others
10115	Chloride liquicolor	Others
10115300	Chloride liquicolor	Others
10118	Potassium liquirapid	Others
10120	Potassium liquiUV	Others
10120300	Potassium liquiUV	Others
10120600	Potassium liquiUV	Others
10121	Glucose liquicolor	Others
10126	Potassium Standard	Others
10229	Iron liquicolor	Others
10230	Iron liquicolor	Others

Cat.-no.	Product name	Class
10260	Glucose liquicolor	Others
10260300	Glucose liquicolor	Others
10260600	Glucose liquicolor	Others
10284	HDL Cholesterol liquicolor	Others
10294	LDL Cholesterol liquicolor	Others
10505	Urea liquicolor	Others
10506	Urea liquicolor R1	Others
10507	Urea liquicolor R2	Others
10521	Urea liquiUV	Others
10521300	Urea liquiUV	Others
10521600	Urea liquiUV	Others
10560	Albumin liquicolor	Others
10560300	Albumin liquicolor	Others
10560600	Albumin liquicolor	Others
10570	Total Protein liquicolor	Others
10570300	Total Protein liquicolor	Others
10570600	Total Protein liquicolor	Others
10590	Urinary Total Protein liquicolor	Others
10590300	Urinary Total Protein liquicolor	Others
10595	Urinary Total Protein Standard	Others
10657, 10658, 10259	Glycohemoglobin HbA_1	Others
10670	TIBC	Others
10690	Uric acid liquicolor	Others
10691	Uric acid liquicolor	Others
10694	Uric acid liquicolor^{Plus}	Others
10694300	Uric acid liquicolor^{Plus}	Others
10694600	Uric acid liquicolor^{Plus}	Others
10720P	Triglycerides liquicolor^{mono}	Others
10724	Triglycerides liquicolor^{mono}	Others
10724300	Triglycerides liquicolor^{mono}	Others
10724600	Triglycerides liquicolor^{mono}	Others
10725	Triglycerides liquicolor^{mono}	Others
10740	Bilirubin D&T liquicolor	Others
10741	auto-Bilirubin-D liquicolor	Others
10741300	auto-Bilirubin-D liquicolor	Others
10741600	auto-Bilirubin-D liquicolor	Others
10742	auto-Bilirubin-T liquicolor	Others
10742300	auto-Bilirubin-T liquicolor	Others
10742600	auto-Bilirubin-T liquicolor	Others
10751	Hemoglobin liquicolor	Others

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	Immunglobulins direct IgA direct Reagent kit	Others
11501300	Immunoglobulins direct IgA	Others
11501600	Immunoglobulins direct IgA	Others
11502	Immunglobulins direct IgG direct Reagent kit	Others
11502300	Immunoglobulins direct IgG	Others
11502600	Immunoglobulins direct IgG	Others
11503	Immunglobulins direct IgM direct Reagent kit	Others
11503300	Immunoglobulins direct IgM	Others
11503600	Immunoglobulins direct IgM	Others

Cat.-no.	Product name	Class
11504	Immunglobulins 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 liquicolor *IFCC*	Others
12211	GOT(ASAT) liquiUV M-Test	Others
12212	GPT(ALAT) liquiUV M-Test	Others
12213	Gamma-GT liquicolor M-Test	Others
12214	LDH liquiUV M-Test	Others
12217	Alk.Phos.liquicolor M-Test	Others
12218	Alpha-Amylase liquicolor M-Test	Others
12290	Iron TPTZ liquicolor	Others
12290300	Iron TPTZ liquicolor	Others
12290600	Iron TPTZ liquicolor	Others
12291	Iron TPTZ liquicolor	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 liquicolor	Others
157004	Total Protein liquicolor	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

Cat.-no.	Product name	Class
50101	Syphilis TPHA liquid	Others
50200, 50201 50211, 50231, 50271, 50281, 50291 50301	HUMATEX Febrile Antigens	Others
51005	Syphilis Screen	Others
51015	IgE total ELISA	Others
51103	CMV IgM ELISA	II, B
51106	Measles IgM ELISA	Others
51110	VZV IgM ELISA	Others
51119	Toxo IgM µ-capture ELISA	II, B
51126	HSV IgM ELISA	Others
51140	Dengue IgM ELISA	Others
51203	CMV IgG ELISA	II, B
51206	Measles IgG ELISA	Others
51208	Rubella IgG	II, B
51209	Toxoplasma g. IgG ELISA	II, B
51210	VZV IgG ELISA	Others
51215	HIV Ag/Ab ELISA	II, A
51216	HSV 1 IgG ELISA	Others
51222	H.Pylori IgG ELISA	Others
51226	HSV 2 IgG ELISA	Others
51240	Dengue IgG ELISA	Others
51275	Anti-HCV ELISA	II, A
51322	H.Pylori IgA ELISA	Others
52010	AFP ELISA	Others
52020	CEA ELISA	Others
52030	PSA ELISA	II, B
52035	fPSA ELISA	II, B
52050	CA 125	Others
52060	CA 19-9	Others
52080	CA 15-3	Others
53010	LH ELISA	Others
53020	FSH ELISA	Others
53030	Prolactin ELISA	Others
53040	hCG ELISA	Others
54010	T3 ELISA	Others
54015	fT3 ELISA	Others
54020	T4 ELISA	Others
54025	fT4 ELISA	Others
54030	TSH ELISA	Others
55010	Testosterone ELISA	Others
55020	Progesterone ELISA	Others
55030	Estradiol ELISA	Others
55040	Estriol ELISA	Others
55050	Cortisol ELISA	Others
55060	DHEA-S ELISA	Others

Cat.-no.	Product name	Class
55500	25-OH Vitamin D	Others
573351	Sodium rapid	Others
58012	Hexagon Chlamydia	II, B
58042	Hexagon Syphilis	Others
58054	Hexagon Malaria	Others
58912	Hexagon Chlamydia Collect	II, B
68004	HumaPreg Urine	Others
68902, 68932	Hexagon hCG 1-Step Urine	Others
82100	HCG HumaCLIA SR	Others
82105	Progesterone HumaCLIA SR	Others
82110	Testosterone HumaCLIA SR	Others
82115	LH HumaCLIA SR	Others
82120	FSH HumaCLIA SR	Others
82125	Prolactin HumaCLIA SR	Others
82130	Estradiol (E2) HumaCLIA SR	Others
82150	AMH HumaCLIA SR	Others
82850	AMH Control HumaCLIA SR	Others
83100	AFP HumaCLIA SR	Others
83105	CEA HumaCLIA SR	Others
83110	CA 125 HumaCLIA SR	Others
83115	CA 15-3 HumaCLIA SR	Others
83120	CA 19-9 HumaCLIA SR	Others
83125	fPSA HumaCLIA SR	II, B
83130	PSA HumaCLIA SR	II, B
84600	TSH HumaCLIA SR	Others
84605	T4 HumaCLIA SR	Others
84610	fT4 HumaCLIA SR	Others
84615	T3 HumaCLIA SR	Others
84620	fT3 HumaCLIA SR	Others
84625	Anti-TG HumaCLIA SR	Others
84630	Anti-TPO HumaCLIA SR	Others
84850	Immunoassay Multi Control HumaCLIA SR	Others
85000	25-OH Vitamin D HumaCLIA SR	Others
85020	PCT HumaCLIA SR	Others
85030	Troponin I HumaCLIA SR	Others
85035	Myoglobin HumaCLIA SR	Others
85040	CK-MB HumaCLIA SR	Others
85050	Ferritin HumaCLIA SR	Others
85055	Vitamin B12 HumaCLIA SR	Others
85820	PCT Control HumaCLIA SR	Others
ITC30300	IMTEC-t-Transglutaminase Anitbodies IgG	Others
ITC30400	IMTEC-t-Transglutaminase Anitbodies IgA	Others
ITC30505	IMTEC-d-Gliadin-Antibodies IgG	Others
ITC30605	IMTEC-d-Gliadin-Antibodies IgA	Others
ITC30701	IMTEC-Gastro-LIA	Others
ITC40040	IMTEC-Salmononella-Antibodies Screen (cut-off)	Others
ITC40050	IMTEC-Salmononella-Antibodies IgA (cut-off)	Others
ITC59001	IMTEC-DsDNA-Antibodies	Others
ITC59011	IMTEC-Phosphatidylserine-Antibodies IgG	Others

Cat.-no.	Product name	Class
ITC59021	IMTEC-Phosphatidylserine-Antibodies IgM	Others
ITC59027	IMTEC-Phosphatidylserine-Antibodies Screen	Others
ITC59031	IMTEC-CIC IgG	Others
ITC59032	IMTEC-C3d-CIC	Others
ITC59033	IMTEC-Anti-C1q-Antibodies	Others
ITC59035	IMTEC-Complement Activity	Others
ITC59050	IMTEC-beta2-Glycoprotein 1-Antibodies Screen	Others
ITC59070	IMTEC-Phospholipid-Antibodies Screen	Others
ITC59071	IMTEC-Cardiolipin-Antibodies IgG	Others
ITC59076	IMTEC-Cardiolipin-Antibodies Screen	Others
ITC59081	IMTEC-Cardiolipin-Antibodies IgM	Others
ITC59082	IMTEC-Cardiolipin-Antibodies Combi	Others
ITC59150	IMTEC-beta2-Glycoprotein 1-Antibodies IgG	Others
ITC59250	IMTEC-beta2-Glycoprotein 1-Antibodies IgM	Others
ITC59400	IMTEC-Phosphatidylethanolamine-Antibodies Screen	Others
ITC59450	IMTEC-Prothrombin-Antibodies Screen	Others
ITC59500	IMTEC-oxLDL-Antibodies Ig(GM)	Others
ITC59550	IMTEC-Annexin V-Antibodies Screen	Others
ITC60001	IMTEC-ANA Screen	Others
ITC60003	IMTEC-RF IgM	Others
ITC60015	IMTEC-RA33-Antibodies	Others
ITC60021	IMTEC-CCP-Antibodies	Others
ITC60029	IMTEC-SmD1-Antibodies IgG	Others
ITC60033	IMTEC-ENA Profile	Others
ITC60040	IMTEC-AMA M2	Others
ITC60201	IMTEC-Myositis LIA PL	Others
ITC66050	IMTEC-LKM1-Antibodies	Others
ITC66205	IMTEC-Liver-LIA S	Others
ITC70001	IMTEC-ANA Screen (cut-off)	Others
ITC70005	IMTEC-ENA Screen (cut-off)	Others
ITC70022	IMTEC-U1-snRNP-Antibodies	Others
ITC70024	IMTEC-SS-B/La-Antibodies	Others
ITC70025	IMTEC-Jo1-Antibodies	Others
ITC70026	IMTEC-SS-A/Ro-Antibodies	Others
ITC70028	IMTEC-Scl70-Antibodies	Others
ITC80001 ITC80002 ITC80003 ITC80004	IMTEC-HumaScan^{FA} Software	Others
ITC82020	IMTEC-PR3-ANCA	Others
ITC82030	IMTEC-MPO-ANCA	Others
ITC82040	IMTEC-Vasculitis-LIA	Others
ITC82070	IMTEC-GBM-Antibodies	Others
ITC85010	IMTEC-TG-Antibodies	Others
ITC85020	IMTEC-TPO-Antibodies	Others
ITC85030	IMTEC-TSH Receptor-Antibodies	Others
ITC92000	IMTEC-ANA-LIA	Others

Cat.-no.	Product name	Class
ITC92000-1	IMTEC-ANA-LIA	Others
ITC92000-2	IMTEC-ANA-LIA	Others
ITC92000-3	IMTEC-ANA-LIA	Others
ITC92000-4	IMTEC-ANA-LIA	Others
ITC92000-5	IMTEC-ANA-LIA	Others
ITC92005	IMTEC-ANA-LIA Maxx	Others
ITC92007	IMTEC-ANA-LIA XL	Others
ITC94000	IMTEC-Arthritis-LIA	Others

Class: acc. to directive 98/79 EC
II, A = test listed in annex II, list A
II, B = test listed in annex II, list B
H = test for home use, not listed in annex II
Others

Class: acc. to regulation 2017/746
red-background = class D
blue-background = class C
green-background = class B

CE 0123

DECLARATION OF CONFORMITY

Manufacturer:	Shanghai Long Island Biotec. Co., Ltd No.839, Gaofeng Road, Fengxian District, 201401 Shanghai, P.R. China
Manufacturer SRN	/
EC Representative:	Shanghai International Holding Corp GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany
Product:	Cleaning Solution I
Catalogue Number:	**CLI1015**
Basic UDI-DI:	**/**
Classification:	Class A(According to Rule 5 of IVDR annex VIII)
Conformity Assessment Route:	Annex IX (excluding CHAPTER II)
GMDN code:	

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

Reference to CS:	**/**
Notified Body:	TUV SUD Product Service GmbH RidlerstraBe 65 80339 Munchen,Germany
Notified Body No.:	0123
Identification of the Certificate:	2022-05-22
Start of CE -Marking:	2009-06-01

I hereby am appointed sa the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Deparment of Shanghai Long Island Biotec. Co., Ltd,Effecctive immediately.

Place,Date of Issue	Shanghai
Signature:	Xi Qimin
Name of Authorized Signatory:	Ms. Xi Qimin
Position Held in Company:	Management Representative

Applied Standards List

Product: Cleaning Solution I

Catalogue Number: CLI1015

Applied Standards:

EN ISO 183113-1:2011	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 1:Terms,definitions and general requirements(ISO 183113-1:2009)
EN ISO 183113-2:2011	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 2:In vitro dignostic reagents for professional use(ISO 183113-2:2009)
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 14971:2012	Medical devices-Application of risk managemt to medical devices(ISO 14971:2007,Corrected version 2007-10-1)
EN 13612:2002/AC:2002	Performance evaluation of in vitrodiagnostic medical devices.
EN iso 23640:2015	In vitro diagnostic medic devices-Evaluation of stability of in vitro diagnostic reagents.
EN13641:2002	Elimination or reduction of risk of infection related to in vitro dignostic reagents.
EN ISO 17511:2003	In vitro diagnostic medic devices-Measurement of quantities in biological samples-Metrological traceability of values assigned to calibrators and control materials(ISO 17511:2003)
EN62366-1:2015	Medical devices-Part1:Application of usability engineering to in vitro diagnostic medic devices.
EN ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 9001:2015	Quality management systems — Requirements

CE 0123

DECLARATION OF CONFORMITY

Manufacturer:	Shanghai Long Island Biotec. Co., Ltd No.839, Gaofeng Road, Fengxian District, 201401 Shanghai, P.R. China
Manufacturer SRN	/
EC Representative:	Shanghai International Holding Corp GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany
Product:	Cleaning Solution II
Catalogue Number:	**CLII102500**
Basic UDI-DI	**/**
Classification	Class A(According to Rule 5 of IVDR annex VIII)
Conformity Assessment Route:	Annex IX (excluding CHAPTER II)
GMDN Code	

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

Reference to CS:	**/**
Notified Body:	TUV SUD Product Service GmbH RidlerstraBe 65 80339 Munchen,Germany
Notified Body No.:	0123
Identification of the Certificate:	2022-05-22
Start of CE -Marking:	2009-06-01

I hereby am appointed sa the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Deparment of Shanghai Long Island Biotec. Co., Ltd,Effecctive immediately.

Place,Date of Issue	Shanghai
Signature:	Xi Qimin
Name of Authorized Signatory:	Ms. Xi Qimin
Position Held in Company:	Management Representative

Applied Standards List

Product: Cleaning Solution II

Catalogue Number: CLII102500

Applied Standards:

EN ISO 183113-1:2011	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 1:Terms,definitions and general requirements(ISO 183113-1:2009)
EN ISO 183113-2:2011	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 2:In vitro dignostic reagents for professional use(ISO 183113-2:2009)
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 14971:2012	Medical devices-Application of risk managemt to medical devices(ISO 14971:2007,Corrected version 2007-10-1)
EN 13612:2002/AC:2002	Performance evaluation of in vitrodiagnostic medical devices.
EN iso 23640:2015	In vitro diagnostic medic devices-Evaluation of stability of in vitro diagnostic reagents.
EN13641:2002	Elimination or reduction of risk of infection related to in vitro dignostic reagents.
EN ISO 17511:2003	In vitro diagnostic medic devices-Measurement of quantities in biological samples-Metrological traceability of values assigned to calibrators and control materials(ISO 17511:2003)
EN62366-1:2015	Medical devices-Part1:Application of usability engineering to in vitro diagnostic medic devices.
EN ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 9001:2015	Quality management systems — Requirements

Declaration of Conformity CE

Manufacturer:	Beijing Precil Instrument Co., Ltd. Room 203,204&401,Building 2,No.2 Tongji Middle Road,Beijing Economic & Technological Development Area,Beijing,100176,China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Product:	Auto Coagulation Analyzer
Model:	C3100
Consumables:	Auto Cuvettes Probe Cleanser Cleanser
Classification:	Others (Not listed in the Annex II, Directive 98/79/EC)

Conformity assessment route: Annex III(Except 6), Directive 98/79/EC

We herewith declare that the above-mentioned products meet the previsions of the following EC Council Directives 98/79/EC for in-vitro-diagnostics. All supporting documentation is retained under the premises of the manufacturer.

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

Start of CE-Marking: 2019-10-28

Place, Date: Beijing, 2019-10-28

Signature:
Name of Authorized Signatory: Ge Pengfei
Position Held in Company: Management Representative

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class A Devices in Sterile Condition)

No. V11 042464 0039 Rev. 00

Manufacturer:

Zhejiang Gongdong Medical Technology Co., Ltd.
No.10 Beiyuan Ave., Huangyan
318020 Taizhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer: CN-MF-000005694

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The involvement of the notified body is limited to the aspects relating to establishing, securing and maintaining sterile conditions.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V11 042464 0039 Rev. 00

Report No.: SH2211102

Valid from: 2023-04-11

Valid until: 2028-04-10

Marta Carnielli
Head of Notified Body IVD

Issue date: 2023-04-11

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class A Devices in Sterile Condition)

No. V11 042464 0039 Rev. 00

Classification:	Class A
Device Group:	W050101 - BLOOD COLLECTION DEVICES
Intended Purpose:	IVR 0803 - Specimen receptacles referred to in point 2.5 (rule 5), under c), of Annex VIII to Regulation (EU) 2017/746
The validity of this certificate depends on conditions and/or is limited to the following:	-

Revision History:

Rev.	Dated	Report	Description
00	2023-04-11	SH2211102	Initial issuance

REPUBLICA MOLDOVA mun. CHIȘINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ECHIPAMED-PLUS" IDNO 1003600077677

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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