

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 ,
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-Deikenheim
Germany



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



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



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
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 Antibodies IgG	Others
ITC30400	IMTEC-t-Transglutaminase Antibodies 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