Human

Gesellschaft für Biochemica
und Diagnostica mbH

Max-Planck-Ring 21
65205 Wiesbaden •Germany

Telefon +49 6122 9988-0
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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 31.12.2019 and is only effective in connection with a valid Distribution Agreement.

Wiesbaden, 7 February 2019

HUMAN Gesellschaft für Biochemica und Diagnostica mbH

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

Dhimitraq Jani
International Sales Manager

"ECHIPAMED-PLUS" IDNO 1003600077677

Certificate

mdc medical device certification GmbH
certifies that

Human

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

for the scope

development, manufacturing and distribution of in vitro diagnostic products and analyzers

has introduced and applies a

Quality management system

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 9001

Quality management systems – Requirements

(ISO 9001:2015)

Valid from	2018-03-16
Valid until	2021-03-15
Registration no.	D1030000066
Report no.	P17-01410-107299
Stuttgart	2018-03-16

Head of Certification Body

medical device certification mdc

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

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Certificate

mdc medical device certification GmbH
certifies that

Human

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

with the production site

Stegelitzer Straße 3
39126 Magdeburg
Germany

for the scope

development, manufacturing and distribution of in vitro diagnostic products and analyzers

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2012 + AC:2012 - ISO 13485:2003 + Cor. 1:2009

Valid from	2014-03-12
Valid until	2019-03-11
Registration no.	D1030000030
Report no.	E-D10300_2014-03-10
Stuttgart	2014-03-10

Head of Certification Body

medical device certification mdc

Akkreditiert durch Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-976.00.03-46

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

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith grants

Human

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

for the scope

HEXAGON HIV (57002P, 57004P) Immunochromatographic rapid test for the qualitative detection of IgM, IgA and IgG antibodies to immune deficiency virus HIV-1 and HIV-2 in human whole blood, serum or plasma

the

EC Design Examination Certificate

The examination of the design of the product by mdc has proven that the design meets the requirements according to

Annex IV – Section 4
of the Council Directive 98/79/EC

of the European Parliament and of the Council of
27 October 1998 on in vitro diagnostic medical devices.

This certificate is only valid in connection with a valid mdc certificate according to Annex IV – excluding section 4 and 6 for the above mentioned products.

Valid from	2014-09-29
Valid until	2019-06-02
Registration no.	D1030000032
Report no.	P14-00929-22354
Stuttgart	2014-09-29

Head of Certification Body

medical device certification mdc

mdc medical device certification GmbH
Kriegerstraße 8
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

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 13485:2012+AC:2012 – ISO 13485:2003 + Cor. 1:2009. 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 D1030000066 and D1030000030).

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.: D1030000067, D1030000028, D1030000032, D1030000048, D1030000049, D1030000062, D1030000063 and D1030000068 respectively).

We further confirm that the IVD products listed in the attachment are designed, manufactured and controlled by us in accordance with the European directive 98/79 EC and that they meet the essential requirements according to annex I of said directive. Applicable conformity assessment procedures according to annex III (denoted others or H in the attached list) or annex IV (denoted II, A or II, B), whatever applicable, of said directive have been completed for these products. We further confirm that for each IVD product an individual conformity declaration has been prepared.

With the CE mark on the listed products we declare in our sole responsibility that the products are in conformity with the applicable directive 98/79/EC and harmonized standards.

HUMAN Gesellschaft für Biochemica und Diagnostica mbH

Date: November 07, 2018

Dr. Torsten Börchers
Vice President Quality Assurance and Regulatory Affairs

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

Attachment

Cat.-no.	Product name	Class
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
55500	25-OH Vitamin D	Others
57002P, 57004P	Hexagon HIV	II, A
573351	Sodium rapid	Others
58002	Hexagon Chagas	Others
58012	Hexagon Chlamydia	II, B
58022	Hexagon H.Pylori	Others
58032	HEXAGON TB	Others
58042	Hexagon Syphilis	Others
58054	Hexagon Malaria	Others
58062	HEXAGON Strep A	Others
58082	HEXAGON Dengue	Others
58912	Hexagon Chlamydia Collect	II, B
60022	Fertitex Mono	Others
68004	Humapreg *Serum/Urine*	Others
68902, 68932	Hexagon hCG 1-Step *Serum/Urine*	Others
71012	HumaType Anti-A	II, A
71022	HumaType Anti-B	II, A
71032	HumaType Anti-A,B	II, A
71042	HumaType Anti-D IgM	II, A
71052	HumaType Anti-D IgM/IgG	II, A
71062	HumaType Anti-Human Globulin	II, B
71072	HumaType Albumin 22%	Others
73005/12	HumaTube No Additive (Z)	Others
73020/12	HumaTube Serum C/A (Z)	Others
73023/12	HumaTube Serum C/A (Z)	Others
73030/12	HumaTube Serum Gel-C/A (Z)	Others
73032/12	HumaTube K2-EDTA (K2E)	Others
73040/12	HumaTube K3-EDTA (K3E)	Others
73045/12	HumaTube K3-EDTA (K3E)	Others
73050/12	HumaTube Li-Heparin (LH)	Others
73060/12	HumaTube Na-Citrate 3.2 % (9NC)	Others
73070/12	HumaTube Glucose (FH)	Others
961000	HumaLoop T	Others
962000	HumaLoop M	Others
963100	HumaTurb A	Others
963200	HumaTurb C + A	Others
964000	HumaHeat	Others

Cat.-no.	Product name	Class
ITC02850	HumaScan	Others
ITC30500	IMTEC-Gliadin-Antibodies IgG	Others
ITC30505	IMTEC-d-Gliadin-Antibodies IgG	Others
ITC30600	IMTEC-Gliadin-Antibodies IgA	Others
ITC30605	IMTEC-d-Gliadin-Antibodies IgA	Others
ITC30701	IMTEC-Gastro-LIA	Others
ITC40040	IMTEC-Salmononella-Antibodies Screen (cut-off)	Others
ITC40050	IMTEC-Salmononella-Antibodies IgA (cut-off)	Others
ITC59001	IMTEC-DsDNA-Antibodies	Others
ITC59002	IMTEC-Nucleosome-Antibodies	Others
ITC59005	IMTEC-ssDNA-Antibodies	Others
ITC59011	IMTEC-Phosphatidylserine-Antibodies IgG	Others
ITC59021	IMTEC-Phosphatidylserine-Antibodies IgM	Others
ITC59022	IMTEC-Phosphatidylserine-Antibodies Combi	Others
ITC59027	IMTEC-Phosphatidylserine-Antibodies Screen	Others
ITC59030	IMTEC-CIC Screen (cut-off)	Others
ITC59031	IMTEC-CIC IgG	Others
ITC59032	IMTEC-C3d-CIC	Others
ITC59033	IMTEC-Anti-C1q-Antibodies	Others
ITC59035	IMTEC-Complement Activity	Others
ITC59050	IMTEC-beta2-Glycoprotein 1-Antibodies Screen	Others
ITC59070	IMTEC-Phospholipid-Antibodies Screen	Others
ITC59071	IMTEC-Cardiolipin-Antibodies IgG	Others
ITC59076	IMTEC-Cardiolipin-Antibodies Screen	Others
ITC59081	IMTEC-Cardiolipin-Antibodies IgM	Others
ITC59082	IMTEC-Cardiolipin-Antibodies Combi	Others
ITC59150	IMTEC-beta2-Glycoprotein 1-Antibodies IgG	Others
ITC59250	IMTEC-beta2-Glycoprotein 1-Antibodies IgM	Others
ITC59400	IMTEC-Phosphatidylethanolamine-Antibodies Screen	Others
ITC59450	IMTEC-Prothrombin-Antibodies Screen	Others
ITC59500	IMTEC-oxLDL-Antibodies Ig(GM)	Others
ITC59550	IMTEC-Annexin V-Antibodies Screen	Others
ITC60000	IMTEC-RF Screen	Others
ITC60001	IMTEC-ANA Screen	Others
ITC60003	IMTEC-RF IgM	Others
ITC60005	IMTEC-ENA Screen	Others
ITC60007	IMTEC-RF IgG	Others
ITC60010	IMTEC-RF IgA	Others
ITC60015	IMTEC-RA33-Antibodies	Others
ITC60021	IMTEC-CCP-Antibodies	Others
ITC60029	IMTEC-SmD1-Antibodies IgG	Others
ITC60031	IMTEC-Histone-Antibodies	Others
ITC60033	IMTEC-ENA Profile	Others
ITC60040	IMTEC-AMA M2	Others