

Certificate of CE-Registration



MDSS

Medical Device Safety Service

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

**Epitope Diagnostics, Inc.
7110 Carroll Road
San Diego, CA 92121
USA**

as stipulated and demanded by the aforementioned Directive. The European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011. The German Competent Authority is notified of the manufacturer's *in vitro* diagnostic medical devices and has allocated registration numbers shown in:

Annex A dated 2020-10-05

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the *in vitro* diagnostic medical devices fulfill the applicable requirements of Directive 98/79/EC. In compliance with German law, a safety officer has been appointed for Germany.

2020-10-05



Dr. Philipp Hohenbrink
Senior Consultant
MDSS GmbH

Manufacturer: Epitope Diagnostics, Inc.

REF	Notified Device Names	EDMA Code (notified)	EDMA Description (notified)	Class. (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
KT-828	EDJ™ Human Fecal GDH ELISA Kit Fecal Sample Collection and Extraction Kit (component of KT- 828)	11 01 01 17 00	Glutamate Dehydrogenase	"Other"	N/A	DE/CA09/0170/E16/IVD/008-01
KT-889		11 01 01 17 00	Glutamate Dehydrogenase	"Other"	N/A	DE/CA09/0170/E16/IVD/008-01
KT-810	EDJ™ Human Pepsinogen I ELISA Kit	11 01 01 90 00	Other Enzymes	"Other"	N/A	DE/CA09/0170/E16/IVD/036-01
KT-811	EDJ™ Human Pepsinogen II ELISA Kit	11 01 01 90 00	Other Enzymes	"Other"	N/A	DE/CA09/0170/E16/IVD/036-01
KT-805	EDJ™ Human Anti-Mouse Antibody (HAMA) ELISA Kit	12 01 01 50 00	Human anti-mouse antibody	"Other"	N/A	DE/CA09/0170/E16/IVD/025-01
KT-806	EDJ™ Human Anti-Human Antibody (HAHA) ELISA Kit	12 01 01 90 00	Other Immunoglobulins	"Other"	N/A	DE/CA09/0170/E16/IVD/024-01
KT-751	EDJ™ HAPTOGLOBIN Immunoturbidimetric Assay Kit	12 01 03 03 00	Haptoglobin	"Other"	N/A	DE/CA09/0170/E16/IVD/019
KT-849	EDJ™ Quantitative Fecal Calprotectin ELISA Kit	12 01 90 10	Calprotectin	"Other"	N/A	DE/CA09/0170/E16/IVD/029-03
KT-843	EDJ™ Calprotectin Sample Collection Kit	12 01 90 10	Calprotectin	"Other"	N/A	DE/CA09/0170/E16/IVD/029-03
KT-843W	Fecal Calprotectin Sample Collection and Extraction Kit	12 01 90 10	Calprotectin	"Other"	N/A	DE/CA09/0170/E16/IVD/029-03
CL0849	EDJ™ Human Calprotectin CLIA Kit	12 01 90 10	Calprotectin	"Other"	N/A	DE/CA09/0170/E16/IVD/029-03
KT-803	Serolisa™ Human Anti-IgE Antibody ELISA Kit	12 02 01 90	Other Allergy Tests	"Other"	N/A	DE/CA09/0170/E16/IVD/048
KT-313	EpiTuub™ iFOB Rapd Test Kit	12 03 90 04 00	Fecal Occult Blood (IC)	"Other"	N/A	DE/CA09/0170/E16/IVD/034-02
KT-313s	EDJ™ Fecal Occult Blood Strip Test Kit	12 03 90 04 00	Fecal Occult Blood (IC)	"Other"	N/A	DE/CA09/0170/E16/IVD/034-02
KT-850, 30210 (collection device)	q-FOB™ Quantitative Fecal Occult Blood Test Kit	12 03 90 04 00	Fecal Occult Blood (IC)	"Other"	N/A	DE/CA09/0170/E16/IVD/034-02
KT-111	FOB Rapid Test Kit	12 03 90 04 00	Fecal Occult Blood (IC)	"Other"	N/A	DE/CA09/0170/E16/IVD/034-02
KT-817	EDJ™ Human Neuron Specific Enolase ELISA Kit	12 03 90 08 00	Neuron Specific Enolase	"Other"	N/A	DE/CA09/0170/E16/IVD/004-01

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KT-812, KT-820, KT-855	EDI™ Human Chromogranin A ELISA Kit	12 03 90 20	Chromogranin A	"Other"	N/A	DE/CA09/0170/E16/IVD/035-01
KT-800	EDI™ Human Fetuin-A ELISA Kit	12 05 02 09 00	Glycoprotein A Subunit	"Other"	N/A	DE/CA09/0170/E16/IVD/037-01
KT-900	EDI™ High Sensitive Human Fetuin-A ELISA Kit	12 05 02 09 00	Glycoprotein A Subunit	"Other"	N/A	DE/CA09/0170/E16/IVD/037-01
KT-804	Serolisa™ Human Anti-Müllerian Hormone ELISA Kit	12 05 02 16	Anti-Müllerian Hormone	"Other"	N/A	DE/CA09/0170/E16/IVD/047
KT-881	EDI™ Human C-peptide ELISA	12 06 01 01	C-Peptide	"Other"	N/A	DE/CA09/0170/E16/IVD/041
KT-891	EDI™ Human Ultra-Sensitive C-Peptide ELISA	12 06 01 01	C-Peptide	"Other"	N/A	DE/CA09/0170/E16/IVD/041
KT-602	EDI™ Total GLP-1 ELISA Kit	12 06 01 02 00	Glucagon	"Other"	N/A	DE/CA09/0170/E16/IVD/018
KT-886	EDI™ Human Insulin ELISA	12 06 01 03 00	Insulin	"Other"	N/A	DE/CA09/0170/E16/IVD/045
KT-879	EDI™ Human Intact FGF-21 ELISA Kit	12 06 01 90 00	Other Diabetes Tests	"Other"	N/A	DE/CA09/0170/E16/IVD/017
KT-853	EDI™ Human NGAL ELISA	12 06 02 07	Neutrophil Gelatinase associated Lipocalin (lipocalin 2)	"Other"	N/A	DE/CA09/0170/E16/IVD/015-02
KT-883	EDI™ Quantitative Plasma NGAL ELISA Kit	12 06 02 07	Neutrophil Gelatinase associated Lipocalin (lipocalin 2)	"Other"	N/A	DE/CA09/0170/E16/IVD/015-02
KT-884	NGAL Sample Collection Kit (incl. Sample Collection devices - 30389)	12 06 02 07	Neutrophil Gelatinase associated Lipocalin (lipocalin 2)	"Other"	N/A	DE/CA09/0170/E16/IVD/015-02
KT-815, KT-715	EDI™ Total 25-OH Vitamin D EIA Kit	12 06 03 10 00	25-Hydroxyvitamin D	"Other"	N/A	DE/CA09/0170/E16/IVD/009-01
KT-809	EDI™ Human Osteocalcin (1-43/49) Specific ELISA Kit	12 06 03 12 00	Osteocalcine	"Other"	N/A	DE/CA09/0170/E16/IVD/005-01
KT-888	Serolisa™ Human Intact PTH ELISA Kit	12 06 03 13	Parathyroid Hormone intact	"Other"	N/A	DE/CA09/0170/E16/IVD/046
KT-896	EDI™ Human VDBP (GC Globulin) ELISA Kit	12 06 03 90 00	Other Bone Metabolism Tests	"Other"	N/A	DE/CA09/0170/E16/IVD/044
KT-882	EDI™ Human ACTH ELISA Kit	12 06 04 01 00	Adrenocorticotrophic Hormone	"Other"	N/A	DE/CA09/0170/E16/IVD/016

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KT-819	EDI™ Human Growth Hormone ELISA Kit	12 06 04 02 00	Human Growth Hormone	"Other"	N/A	DE/CA09/0170/E16/IVD/014
KT-706	EDI™ Trastuzumab Emtansine EIA Kit	12 08 05 90 00	Other Anti-neoplastic TDM	"Other"	N/A	DE/CA09/0170/E16/IVD/006
KT-705	EDI™ Intact Brentuximab Vedotin ELISA Kit	12 08 05 90 00	Other Anti-neoplastic TDM	"Other"	N/A	DE/CA09/0170/E16/IVD/006
KT-833	EDI™ High Sensitive Anti-TPO ELISA Kit	12 10 03 01 00	Thyroid Peroxidase (incl. Microsomal) Antibodies	"Other"	N/A	DE/CA09/0170/E16/IVD/001-01
KT-832	EDI™ High Sensitive Anti-Tg (Thyroglobulin) IgG ELISA Kit	12 10 03 04 00	Thyroglobulin Autoantibody	"Other"	N/A	DE/CA09/0170/E16/IVD/002-01
KT-830	EDI™ Human Anti-Gliadin IgA ELISA Kit	12 10 90 06 00	Gliadin Antibodies	"Other"	N/A	DE/CA09/0170/E16/IVD/003-01
KT-831	EDI™ Human Anti-Gliadin IgG ELISA Kit	12 10 90 06 00	Gliadin Antibodies	"Other"	N/A	DE/CA09/0170/E16/IVD/003-01
KT-840	EDI™ Human Anti-Calcium Sensor Receptor (CaSR) Antibody (IgG) ELISA Kit	12 10 90 90 00	Other Other Auto-Immune Disease Tests	"Other"	N/A	DE/CA09/0170/E16/IVD/031-01
KT-890	EDI™ Quantitative Serum/Plasma Myeloperoxidase ELISA Kit	12 13 01 12	Myeloperoxidase	"Other"	N/A	DE/CA09/0170/E16/IVD/020
KT-880	EDI™ Quantitative Fecal/Urine Myeloperoxidase ELISA Kit	12 13 01 12	Myeloperoxidase	"Other"	N/A	DE/CA09/0170/E16/IVD/020
KT-920	EpiTuub® Calprotectin Rapid Test Kit	12 70 01 90 00	Other Specific Proteins Rapid Tests	"Other"	N/A	DE/CA09/0170/E16/IVD/027-02
KT-922	EpiTuub® Calprotectin/i-FOB DUO Rapid Test Kit	12 70 01 90 00	Other Specific Proteins Rapid Tests	"Other"	N/A	DE/CA09/0170/E16/IVD/027-02
KT-112	eCasset™ Calprotectin Rapid Test Kit	12 70 01 90 00	Other Specific Proteins Rapid Tests	"Other"	N/A	DE/CA09/0170/E16/IVD/027-02
FPC-200	Fecal Ova/Parasite Concentration Kit	14 05 01 01	Parasitology Extraction Reagents	"Other"	N/A	DE/CA09/0170/E16/IVD/028-01
KT-839	EDI™ Fecal Cryptosporidium parvum Antigen ELISA Kit	14 05 02 03 00	Cryptosporidium	"Other"	N/A	DE/CA09/0170/E16/IVD/013

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KT-929	EpiTuub™ Fecal H. pylori Antigen Test Kit	15 01 04 01 00	H. Pylori Antigen Detection	"Other"	N/A	DE/CA09/0170/E16/IVD/030-01
KT-824	EDI™ Fecal H. pylori Antigen ELISA Kit	15 01 04 01 00	H. Pylori Antigen Detection	"Other"	N/A	DE/CA09/0170/E16/IVD/030-01
KT-826	EDI™ Fecal Helicobacter Pylori Antigen ELISA Kit	15 01 04 01 00	H. Pylori Antigen Detection	"Other"	N/A	DE/CA09/0170/E16/IVD/030-01
KT-864	Fecal Sample Collection and Extraction Kit (component of KT-826)	15 01 04 01 00	H. Pylori Antigen Detection	"Other"	N/A	DE/CA09/0170/E16/IVD/030-01
KT-854	H. pylori Sample Collection Test Kit	15 01 04 01 00	H. Pylori Antigen Detection	"Other"	N/A	DE/CA09/0170/E16/IVD/030-01
KT-1015	EDI™ Helicobacter Pylori IgG ELISA Kit	15 01 04 03	H.pylori Antibody Assays	"Other"	N/A	DE/CA09/0170/E16/IVD/055
KT-932, K932.10	EpiTuub® Fecal Campylobacter Antigen Rapid Test Kit	15 01 14 01 00	Campylobacter Direct Antigen Detection	"Other"	N/A	DE/CA09/0170/E16/IVD/007
KT-935	EpiTuub® Fecal C. difficile Antigen Rapid Test (incl. Fecal Specimen Collection Device-30389)	15 01 90 02 00	Clostridium difficile	"Other"	N/A	DE/CA09/0170/E16/IVD/011-01
KT-836	Epilisa™ Fecal C. difficile Toxin A & B ELISA	15 01 90 02 00	Clostridium difficile	"Other"	N/A	DE/CA09/0170/E16/IVD/011-01
KT-869	EDI™ Total HAV Antibody ELISA Kit	15 02 01 04	HAV Antibody (Total)	"Other"	N/A	DE/CA09/0170/E16/IVD/038
KT-867	EDI™ Direct & Quantitative HAV Antibody (IgG) ELISA Kit	15 02 01 05	HAV Antibody IgG	"Other"	N/A	DE/CA09/0170/E16/IVD/039
KT-868	EDI™ Hepatitis A Virus IgM ELISA Kit	15 02 01 06	HAV Antibody IgM	"Other"	N/A	DE/CA09/0170/E16/IVD/040
KT-1017	EDI™ Hepatitis E Virus Total Antibody ELISA Kit	15 02 05 04 00	HEV Antibody (Total)	"Other"	N/A	DE/CA09/0170/E16/IVD/021
KT-1018	EDI™ Hepatitis E Virus IgG ELISA Kit	15 02 05 05 00	HEV Antibody IgG	"Other"	N/A	DE/CA09/0170/E16/IVD/022

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KT-1019	EDI™ Hepatitis E Virus IgM ELISA Kit	15 02 05 06 00	HEV Antibody IgM	"Other"	N/A	DE/CA09/0170/E16/IVD/023
KT-1027	Serilosa™ Herpes Simplex Virus Type I & II (HSV-1+2) IgM ELISA Kit	15 04 03 06	HSV 1+2 IgM	"Other"	N/A	DE/CA09/0170/E16/IVD/049
KT-918	EpiTuub™ Fecal Adenovirus Antigen Test Kit	15 04 80 01 00	Adenovirus	"Other"	N/A	DE/CA09/0170/E16/IVD/032-02
KT-842	EDI™ Fecal Adenovirus Antigen ELISA Kit	15 04 80 01 00	Adenovirus	"Other"	N/A	DE/CA09/0170/E16/IVD/032-02
KT-918s	Fecal Adenovirus Antigen Strip Test Kit	15 04 80 01 00	Adenovirus	"Other"	N/A	DE/CA09/0170/E16/IVD/032-02
KT-917	EpiTuub® Fecal Rotavirus Antigen Rapid Test Kit	15 04 80 06 00	Rotavirus	"Other"	N/A	DE/CA09/0170/E16/IVD/033-02
KT-917s	EDI™ Fecal Rotavirus Antigen Strip Test Kit	15 04 80 06 00	Rotavirus	"Other"	N/A	DE/CA09/0170/E16/IVD/033-02
KT-841	EDI™ Fecal Rotavirus Antigen ELISA Kit	15 04 80 06 00	Rotavirus	"Other"	N/A	DE/CA09/0170/E16/IVD/033-02
KT-916	EpiTuub® Fecal Norovirus Antigen Rapid Test (incl. Fecal Specimen Collection Device-30389)	15 04 80 16	Norovirus	"Other"	N/A	DE/CA09/0170/E16/IVD/010
KT-1032	EDI™ Novel Coronavirus COVID-19 IgG ELISA Kit	15 04 80 19	Coronavirus	"Other"	N/A	DE/CA09/0170/E16/IVD/051-01
KT-1033	EDI™ Novel Coronavirus COVID-19 IgM ELISA Kit	15 04 80 19	Coronavirus	"Other"	N/A	DE/CA09/0170/E16/IVD/051-01
KT-1034	EDI™ COVID-19 Nucleocapsid IgG Quantitative ELISA Kit	15 04 80 19	Coronavirus	"Other"	N/A	DE/CA09/0170/E16/IVD/051-01
KT-928; KT-928.10	EpiTuub Fecal Cryptosporidium parvum Antigen Rapid Test	15 05 10 07 00	Cryptosporidium	"Other"	N/A	DE/CA09/0170/E16/IVD/043-01
KT-928s	Fecal Cryptosporidium parvum Antigen Rapid Test Kit	15 05 10 07 00	Cryptosporidium	"Other"	N/A	DE/CA09/0170/E16/IVD/043-01

Manufacturer: Epitepe Diagnostics, Inc.

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KT-845	EDI™ Human Anti-Giardia lamblia IgA ELISA Kit	15 05 10 08 00	Giardia lamblia	"Other"	N/A	DE/CA09/0170/E16/IVD/026-01
KT-847	EDI™ Human Anti-Giardia lamblia IgM ELISA Kit	15 05 10 08 00	Giardia lamblia	"Other"	N/A	DE/CA09/0170/E16/IVD/026-01
KT-846	EDI™ Human Anti-Giardia lamblia IgG ELISA Kit	15 05 10 08 00	Giardia lamblia	"Other"	N/A	DE/CA09/0170/E16/IVD/026-01
KT-838	EDI™ Fecal Giardia lamblia Antigen ELISA Kit	15 05 10 08 00	Giardia lamblia	"Other"	N/A	DE/CA09/0170/E16/IVD/026-01
KT-927	EpiTuub™ Fecal Giardia lamblia Antigen Test Kit	15 05 10 08 00	Giardia lamblia	"Other"	N/A	DE/CA09/0170/E16/IVD/026-01
KT-930; KT-931	EpiTuub® HAV Rapid Test Kit	15 70 02 90 00	Other Hepatitis Viruses- RT & POC	"Other"	N/A	DE/CA09/0170/E16/IVD/042
ECL 100	ECL 100	21 02 10 01	IC&II Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/E16/IVD/050-01
CL011	EDI™ ECL100 Cuvettes	21 02 10 01	IC&II Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/E16/IVD/050-01
30518	EpiTwist™	21 07 10 09	Other RT_CI Hardware + dedicated accessories + consumables + software	"Other"	N/A	DE/CA09/0170/E16/IVD/012
L0504, L0505	Calprotectin Calibrators	12 50 03 05	Specific Protein Standards and Calibrators	"Other"	N/A	DE/CA09/0170/E16/IVD/054
L0506 L0507	Calprotectin Controls	12 50 01 06	Specific Protein Controls	"Other"	N/A	DE/CA09/0170/E16/IVD/053
30356	Calprotectin Sample Collection Tube	51 09 10 01	Other containers for samples of human origin	"Other"	N/A	DE/CA09/0170/E16/IVD/052