

Annex 1

List of devices produced XEMA Co., Ltd.
 registered in German (BfArM-DMIDS) with CE marking

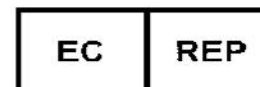
XEMA Co., Ltd.
 bld.48/4, 9th Parkovaya str.
 Moscow 105264, RUSSIA,
 info@xema.ru; www.xema.ru



	Nomenclature term	Catalog number	Short name:	EDMA Classification	Class	Form number All changed by 00313369	Registration number	Certificate number	Registration date	Exp. date
1.	THYROID PEROXIDASE (INCL. MICROSOMAL) ANTIBODIES	K131	aTPO EIA Cat. Nr K131	12-10-03-01-00	other	00082228	DE/CA59/IVD/13/44	00055095	2007-10-29	2025-05-25
2.	THYROGLOBULIN AUTOANTIBODIES	K132	aTG EIA Cat. Nr K132	12-10-03-04-00	other	00082229	DE/CA59/IVD/13/43	00055096	2007-10-29	
3.	MPO ANCA	K133	aMPO EIA Cat. Nr K133	12-10-90-09-00	other	00082229	DE/CA59/IVD/13/42	00055097	2007-10-29	
4.	TISSUE TRANSGLUTAMINASE ANTIBODIES	K160; K161	Anti-tTG IgG EIA Cat. Nr K160; Anti-tTG IgA EIA Cat. Nr K161	12-10-90-21-00	other	00082231	DE/CA59/IVD/13/41	00055098	2007-10-29	
5.	GLIADIN ANTIBODIES	K180; K181; K182A, K182G	Gliadin IgG EIA Cat. Nr K180; Gliadin IgA EIA Cat. Nr K181 ; Deamidated Gliadin IgA EIA, Deamidated Gliadin IgG EIA	12-10-90-06-00	other	00082232/ changed by 00120956	DE/CA59/IVD/13/40	00055099	2011-08-11	
6.	IMMUNOGLOBULIN E – TOTAL	K200	Total IgE EIA Cat. Nr K200	12-02-01-02-00	other	00082233	DE/CA59/IVD/13/39	00055100	2007-10-29	
7.	THYROID STIMULATING HORMONE	K201; K201A	TSH EIA Cat. Nr K201; TSH Plus EIA Cat. Nr K201A	12-04-01-11-00	other	00082237	DE/CA59/IVD/13/38	00055103	2007-10-29	
8.	LUTEINISING HORMONE	K202	LH EIA Cat. Nr K202	12-05-01-05-00	other	00082238	DE/CA59/IVD/13/37	00055104	2007-10-29	
9.	FOLLICLE STIMULATING HORMONE	K203	FSH EIA Cat. Nr K203	12-05-01-04-00	other	00082239	DE/CA59/IVD/13/36	00055105	2007-10-29	
10.	HUMAN GROWTH HORMONE	K204	GH EIA Cat. Nr K204	12-06-04-02-00	other	00082240	DE/CA59/IVD/13/35	00055106	2007-10-29	
11.	HUMAN CHORIONIC GONADOTROPIN TOTAL	K205	HCG EIA Cat. Nr K205	12-05-02-05-00	other	00082241	DE/CA59/IVD/13/34	00055107	2007-10-29	
12.	PROLACTIN	K206	Prolactin EIA Cat. Nr K206	12-05-01-08-00	other	00082242	DE/CA59/IVD/13/33	00055108	2007-10-29	
13.	PROGESTERONE	K207; K207S	Progesterone EIA Cat. Nr K207 ; Salivary Progesterone EIA	12-05-01-06-00	other	00082243/ changed by 00120953	DE/CA59/IVD/13/32	00055109	2011-08-11	
14.	ESTRADIOL	K208	Estradiol EIA Cat. Nr K208	12-05-01-03-00	other	00082244	DE/CA59/IVD/13/31	00055110	2007-10-29	
15.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K209 ; K209S	Testosterone EIA Cat. Nr K209 ; Salivary Testosterone EIA	12-05-01-10-00	other	00082245/ changed by 00120954	DE/CA59/IVD/13/30	00055111	2011-08-11	
16.	CORTISOL	K210 ; K210S	Cortisol EIA Cat. Nr K210 ; Salivary Cortisol EIA	12-06-02-04-00	other	00082246/ changed by 00120955	DE/CA59/IVD/13/29	00055112	2011-08-11	
17.	TRIIODOTHYRONINE	K211	T3 EIA Cat. Nr K211	12-04-01-05-00	other	00082247	DE/CA59/IVD/13/28	00055113	2007-10-29	
18.	THYROXINE	K212	T4 EIA Cat. Nr K212	12-04-01-07-00	other	00082248	DE/CA59/IVD/13/27	00055114	2007-10-29	
19.	FREE TRIIODOTHYRONINE	K213	Free T3 EIA Cat. Nr K213	12-04-01-01-00	other	00082250	DE/CA59/IVD/13/26	00055115	2007-10-29	
20.	FREE THYROXINE	K214	Free T4 EIA Cat. Nr K214	12-04-01-02-00	other	00082251	DE/CA59/IVD/13/25	00055116	2007-10-29	
21.	DEHYDRO-EPIANDROSTERONE SULPHATE (INCL. DHEA)	K215	DHEA-S EIA Cat. Nr K215	12-05-01-02-00	other	00082253	DE/CA59/IVD/13/24	00055117	2007-10-29	
22.	17 OH PROGESTERONE	K217	17-OH-Progesterone EIA Cat. Nr K217	12-05-01-07-00	other	00082256	DE/CA59/IVD/13/22	00055118	2007-10-29	
23.	CANCER ANTIGEN 125	K222	CA 125 EIA Cat. Nr K222	12-03-01-06-00	other	00082257	DE/CA59/IVD/13/23	00055119	2007-10-29	
24.	CANCER ANTIGEN 19-9	K223	CA 19.9 EIA Cat. Nr K223	12-03-01-03-00	other	00082258	DE/CA59/IVD/13/21	00055120	2007-10-29	
25.	CARCINOEMBRYONIC ANTIGEN	K224	CEA EIA Cat. Nr K224	12-03-01-31-00	other	00082262	DE/CA59/IVD/13/20	00055123	2007-10-29	
26.	ALPHAFETOPROTEIN	K225	AFP EIA Cat. Nr K225	12-03-90-01-00	other	00082264	DE/CA59/IVD/13/19	00055124	2007-10-29	
27.	CANCER ANTIGEN 15-3	K226	M12 (CA 15.3) EIA Cat. NrK226	12-03-01-02-00	other	00082265	DE/CA59/IVD/13/18	00055125	2007-10-29	

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28.	OTHER CANCER ANTIGENS	K227; K228	MUC11 M22 EIA Cat. Nr K227; MUC11 M20 EIA Cat. Nr K228	12-03-01-90-00	other	00082266	DE/CA59/IVD/13/17	00055126	2007-10-29	2025-05-25
29.	OTHER OTHER TUMOUR MARKERS	K232	Thyroglobulin EIA Cat. Nr K232	12-03-90-90-00	other	00082267	DE/CA59/IVD/13/16	00055127	2007-10-29	
30.	β HUMAN CHORIONIC GONADOTROPIN (INCL. SUBUNIT)	K235	Free beta HCG EIA Cat. Nr K235	12-05-02-06-00	other	00082268	DE/CA59/IVD/13/15	00055128	2007-10-29	
31.	PREGNANCY ASSOCIATED PLASMA PROTEIN - A (DOWNS)	K238	PAPP-A EIA Cat. Nr K238	12-05-02-10-00	other	00082269	DE/CA59/IVD/13/14	00055129	2007-10-29	
32.	OTHER OTHER PLASMA PROTEINS	K240	Alveomucin EIA Cat. Nr K240	12-01-90-90-00	other	00082270	DE/CA59/IVD/13/13	00055130	2007-10-29	
33.	C-REACTIVE PROTEIN	K250	CRP EIA Cat. Nr K250	12-11-01-09-00	other	00082271	DE/CA59/IVD/13/12	00055131	2007-10-29	
34.	SEX HORMONE BINDING GLOBULIN	K268	SHBG EIA Cat. Nr K268	12-05-01-09-00	other	00082272	DE/CA59/IVD/13/11	00055132	2007-10-29	
35.	TROPONIN (T + I)	K291	Troponin I EIA Cat. Nr K291	12-13-01-07-00	other	00082273	DE/CA59/IVD/13/10	00055133	2007-10-29	
36.	IMMUNOGLOBULIN G	K271	Total IgG EIA Cat. Nr K271	12-01-01-05-00	other	00082274	DE/CA59/IVD/13/9	00055134	2007-10-29	
37.	IMMUNOGLOBULIN G SUBCLASS REAGENTS	K272; K274	IgG2 EIA Cat. Nr K272; IgG4 EIA Cat. Nr K274	12-01-01-06-00	other	00082275	DE/CA59/IVD/13/8	00055135	2007-10-29	
38.	IMMUNOGLOBULIN A	K275	Total IgA EIA Cat. Nr K275	12-01-01-01-00	other	00082276	DE/CA59/IVD/13/7	00055136	2007-10-29	
39.	IMMUNOGLOBULIN M	K277	Total IgM EIA Cat. Nr K277	12-01-01-07-00	other	00082277	DE/CA59/IVD/13/6	00055137	2007-10-29	
40.	RHEUMATOID/AUTOIMMUNE CONTROLS	KQ13; KQ14; KQ15	AutoQon AT immunoassay control set Cat. Nr KQ13; AutoQon ANA/ENA immunoassay control set Cat. Nr KQ14; AutoQon ACL immunoassay control set Cat. Nr KQ15	12-50-01-14-00	other	00082278	DE/CA59/IVD/13/5	00055138	2007-10-29	
41.	HORMONE CONTROLS	KQ21	HormoQon immunoassay control set Cat. Nr KQ21	12-50-01-04-00	other	00082279	DE/CA59/IVD/13/4	00055139	2007-10-29	
42.	TUMOUR MARKER CONTROLS	KQ22	OmaQon immunoassay control set Cat. Nr KQ22	12-50-01-10-00	other	00082280	DE/CA59/IVD/13/3	00055140	2007-10-29	
43.	CYFRA 21-1	K236	CYFRA 21-1 EIA	12-03-01-20-00	other	00120946	DE/CA59/IVD/13/45	00078973	2011-08-11	
44.	CANCER ANTIGEN 72-4	K244	CA 72-4 EIA	12-03-01-05-00	other	00120947	DE/CA59/IVD/13/46	00078974	2011-08-11	
45.	NEONATAL THYROID STIMULATING HORMONE	K201N	TSH-Neo EIA	12-04-01-03-00	other	00120948	DE/CA59/IVD/13/47	00078975	2011-08-11	
46.	ESTRIOL	K218	Free Estriol EIA	12-05-02-02-00	other	00120950	DE/CA59/IVD/13/48	00078977	2011-08-11	
47.	IMMUNOGLOBULIN E - MONOTEST/MONORESULT - MULTI AG	K200S	Specific IgE EIA	12-02-01-04-00	other	00120951	DE/CA59/IVD/13/49	00078978	2011-08-11	
48.	KAPPA AND LAMBDA CHAIN	K279K K279L	Free kappa Igg light chain EIA, Free lambda Igg light chain EIA	12-01-01-20-00	other	00120952	DE/CA59/IVD/13/50	00078979	2011-08-11	
49.	TRYPSIN NEONATAL	K242	Neonatal IRT EIA Cat. Nr K242	12-01-90-08-00	other	00125311	DE/CA59/IVD/13/51	00081283	2013-01-09	
50.	NEURON SPECIFIC ENOLASE	K234	NSE EIA Cat. Nr K234	12-03-90-08-00	other	00126089	DE/CA59/IVD/13/52	00081687	2013-03-20	
51.	OTHER OTHER TUMOUR MARKERS	K239	HE – 4 EIA Cat. Nr K239	12-03-90-90-00	other	00126090	DE/CA59/IVD/13/53	00081688	2013-03-20	
52.	HSV IgG	K104	HSV ½ IgG EIA (Cat. Nr K104)	15-04-03-05-00	other	00127648	DE/CA59/IVD/13/67	00082628	2013-09-10	
53.	HSV IgM	K104M	HSV ½ IgM EIA (Cat. Nr K104M)	15-04-03-06-00	other	00127649	DE/CA59/IVD/13/66	00082629	2013-09-10	
54.	MYCOPLASMA ANTIBODY ASSAYS	K106	Mycoplasma IgG EIA (Cat. Nr K106)	15-01-08-03-00	other	00127650	DE/CA59/IVD/13/65	00082630	2013-09-10	
55.	SYPHILIS ANTIBODY ASSAYS TOTAL	K111	Treponema pallidum Total Ab EIA (Cat. Nr K111)	15-01-03-03-00	other	00127651	DE/CA59/IVD/13/64	00082631	2013-09-10	

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56.	SYPHILIS ANTIBODY IGG	K111G	Treponema pallidum IgG EIA (Cat. Nr K111G)	15-01-03-05-00	other	00127652	DE/CA59/IVD/13/63	00082632	2013-09-10	2025-05-25
57.	SYPHILIS ANTIBODY IGM	K111M	Treponema pallidum IgM EIA (Cat. Nr K111M)	15-01-03-06-00	other	00127653	DE/CA59/IVD/13/62	00082633	2013-09-10	
58.	H. PYLORI ANTIBODY ASSAYS	K119	H.pylori IgG EIA (Cat. Nr K119)	15-01-04-03-00	other	00127654	DE/CA59/IVD/13/61	00082634	2013-09-10	
59.	H. PYLORI ANTIBODY ASSAYS	K119M	H.pylori IgM EIA (Cat. Nr K119M)	15-01-04-03-00	other	00127655	DE/CA59/IVD/13/60	00082635	2013-09-10	
60.	ASPERGILLUS	K121	Aspergillus IgG EIA (Cat. Nr K121)	15-06-01-01-00	other	00127656	DE/CA59/IVD/13/59	00082636	2013-09-10	
61.	OTHER OTHER BACTERIOLOGY IMMUNOASSAY	K126	Ureaplasma IgG EIA (Cat. Nr K126)	15-01-90-90-00	other	00127657	DE/CA59/IVD/13/58	00082637	2013-09-10	
62.	GIARDIA LAMBLIA	K171 K171X	Giardia lamblia Total Ab EIA (Cat. Nr 171); Giardia lambliaIgG/IgM/IgA EIA (Cat. No. K171X)	15-05-10-08-00	other	00127658 changed by 00147228	DE/CA59/IVD/13/57Ä1	00082638 changed by 00082638	2013-09-10 changed 2019-02-27	
63.	OTHER TUMOUR MARKER RAPID TESTS	X220V	XEMAtestOvaScreen (Cat. Nr X220V)	12-70-03-90-00	other	00127659	DE/CA59/IVD/13/56	00082639	2013-09-10	
64.	OTHER TUMOUR MARKER RAPID TESTS	X222	XEMAtestCA125 (Cat. Nr X222)	12-70-03-90-00	other	00127660	DE/CA59/IVD/13/55	00082640	2013-09-10	
65.	OTHER TUMOUR MARKER RAPID TESTS	X239	XEMAtestHE4 (Cat. Nr X239)	12-70-03-90-00	other	00127661	DE/CA59/IVD/13/54	00082641	2013-09-10	
66.	IMMUNOGLOBULIN A IgA	K276	SECRETORY IgA (sIgA) EIA (Cat. No. K276)	12-01-01-01-00	other	00132459	DE/CA59/IVD/13/68	00084857	2014-12-15	
67.	ECHINOCOCCUS	K175	Cestodes IgG EIA (Cat. No. K175)	15-05-10-04-00	other	00137730	DE/CA59/IVD/13/72E	00087715	2016-09-08	
68.	DISTOMATOSIS	K176	Fasciola IgG EIA (Cat. No. K176)	15-05-10-03-00	other	00137731	DE/CA59/IVD/13/71E	00087716	2016-09-08	
69.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K219	Free Testosterone EIA (Cat. No. K219)	12-05-01-10-00	other	00137732	DE/CA59/IVD/13/70E	00087717	2016-09-08	
70.	HUMAN PLACENTAL LACTOGEN HPL	K246	Human Placental Lactogen EIA (Cat. No. K246)	12-05-02-07-00	other	00137733	DE/CA59/IVD/13/69E	00087718	2016-09-08	
71.	CANCER ANTIGEN 242	K243	CA 242 EIA (Cat. No. K243)	12-03-01-08-00	other	00139880	DE/CA59/IVD/13/73	00088906	2017-04-11	
72.	INSULIN	K267N	Insulin EIA (Cat. No. K267N)	12-06-01-03-00	other	00145610	DE/CA59/IVD/13/77	00091667	2018-10-05	
73.	C-PEPTIDE	K267C	C-peptide EIA(Cat. No. K267C)	12-06-01-01-00	other	00145608	DE/CA59/IVD/13/76	00091665	2018-10-05	
74.	OTHER PREGNANCY TESTING HORMONES	K245	AMH EIA (Cat. No. K245)	12-05-02-90-00	other	00145607	DE/CA59/IVD/13/75	00091664	2018-10-05	
75.	SQUAMOUS CELL CARCINOMA ANTIGEN	K237	SCC(A) EIA (Cat. No. K237)	12-03-01-35-00	other	00145606	DE/CA59/IVD/13/74	00091663	2018-10-05	
76.	ASPERGILLUS	K021	GalM Ag EIA (Cat. No. K021)	15-06-01-01-00	other	00147229	DE/CA59/IVD/13/78	00092318	2019-02-27	



Polmed.de, Beata Rozwadowska
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Germany email: info@polmed.de

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
282710-2019-AQ-MCW-FINAS

Initial certification date:
14 February 2019

Valid:
15 February 2022 – 14 February 2025

This is to certify that the management system of
XEMA Co, LTD
bld. 48, 9-th Parkovaya str., Moscow, Russian Federation, 105264
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:
ISO 9001:2015

This certificate is valid for the following scope:

Design and development, manufacturing and sales of in vitro tests for food and feed control, clinical and veterinary diagnostics and forensic investigations.

Place and date:
Espoo, 14 February 2022



For the issuing office:
DNV - Business Assurance
Keilaranta 1, 02150 Espoo, Finland



Kimmo Haarala
Management Representative

Appendix to Certificate

XEMA Co, LTD

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
XEMA Co, LTD	bld. 48, 9-th Parkovaya str., Moscow, Russian Federation, 105264	Design and development, manufacturing and sales of in vitro tests for food and feed control, clinical and veterinary diagnostics and forensic investigations.
XEMA Co, LTD (production site)	2B, Trubetskaya str., Balashikha, Moscow region, Russian Federation, 125000	Design and development, manufacturing and sales of in vitro tests for food and feed control, clinical and veterinary diagnostics and forensic investigations.



XEMA

ООО «ХЕМА»
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10.02.2022

Исх. № 10-01/02

STATEMENT

We, XEMA Co., Ltd. Having a registered office at 48, 9th Parkovaya st., 104264 Moscow, Russia, assign Sanmedico Srl. Having a registered office at srt. A. Corobceanu 7A, apt. 9, Chişinău MD 2012, Moldova, as authorized representative in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC and 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Signature:



Dmitry S. Kostrikin

Deputy general manager