Polmed.de

Vertretung und Repräsentanz

Certificate

Of Marketing Authorization of Medical Product

within Germany, the member states of the European Union
and the other states having a contractual agreement with the European Economic Area

Nr. AR/IVD/Xema/01/2022

Issued on the basis of the Declaration of conformity and registration taking into account account Article 11 of Regulation (EU) 2017/746 (IVDR) on In Vitro Diagnostic, and Medical Device Implementing Act (MPDG)

Ausgestellt auf Grund der Konformitätserklärung und Registrierung unter Berücksichtigung der der Verordnung (EU) 2017/746 (IVDR) über In-vitro-Diagnostika und Medizinprodukterecht-Durchführungsgesetz (MPDG)

Manufacturer / Hersteller	**Xema Co., Ltd.** bld.4, 48, The 9th Parkovaya str. Moscow 105264, RUSSIA, info@xema.ru; www.xema.ru
Product name / Produkt	**See annex to the Certificate** Siehe Anhang zum Zertifikat
Product Classification: Produktklassifizierung	**In Vitro Diagnostic Medical Devices** In-vitro-Diagnostikum (IVD) Medizinprodukte
Category: Kategorie	**Common/ Other IVD** Sonstige IVD-Produkte
Conformity assessment procedure: Konformitatsbewertungsverfahren:	**EC DECLARATION OF CONFORMITY** **(Annex III, except point 6, Directive 98/79/EC)** **in connection with article 110(3) IVDR** **EU- KONFORMITATSERKLARUNG** (Anhang III, außer Nummer 6, Richtlinie 98/79 / EG) in Verbindung mit Artikel 110 (3) IVDR
State Competent Authority: Staatliche Zuständige Behörde	**BfArM** Federal Institute for Drugs and Medical Devices DMIDS (German Medical Device Information and Database System) **BfArM** Das Bundesinstitut für Arzneimittel und Medizinprodukte DMIDS (Deutsches Medizinprodukte-Informations- und Datenbanksystem)

Date of issue : **2022-05-26**
Das Ausstellungsdatum

Valid to : **2025-05-25**
Gültig bis

Represented in the EC by:

Polmed.de Beata Rozwadowska
Fichtenstr. 12a, 90763 Fürth, Germany
email: info@polmed.de
Tel: +49 911 9679677

Digitally signed by Manastîrschii Viorica
Date: 2022.09.07 15:35:22 EEST
Reason: MoldSign Signature
Location: Moldova

Beata Rozwadowska * Polmed.de * Fichtenstr. 12a, 90763 Fürth, Germany

Polmed.de

Valid with the Extract from the database www.dimdi.de (German Medical Device Information and Database System (DMIDS))
Gilt nur mit :Auszug aus der Datenbank www.dimdi.de (Deutsches Medizinprodukte-Informations- und Datenbanksystem (DMIDS))

Polmed.de

Vertretung und Repräsentanz

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVD/Xema/01/2022

The following medical devices can be placed on the market in the Federal Republic of Germany, in the member states of the European Economic Community (EEC) and in the other contract states of the agreement about the European Economic Area.

Die folgenden Medizinprodukte in der Bundesrepublik Deutschland, in den Mitgliedsstaaten der Europäischen Wirtschaftsgemeinschaft (EG) und in den Vertragsstaaten der EG in den Verkehr gebracht werden dürfen.

	Nomenclature term Nomenklaturbezeichnung	Catalog No. Katalog-Nr.	Name of device Produktbezeichnung	DMIDS Registration number Registriernummer
1.	THYROID PEROXIDASE (INCL. MICROSOMAL) ANTIBODIES	K131	aTPO EIA Cat. Nr K131	**DE/CA59/IVD/13/44**
2.	THYROGLOBULIN AUTOANTIBODIES	K132	aTG EIA Cat. Nr K132	**DE/CA59/IVD/13/43**
3.	MPO ANCA	K133	aMPO EIA Cat. Nr K133	**DE/CA59/IVD/13/42**
4.	TISSUE TRANSGLUTAMINASE ANTIBODIES	K160 K161	Anti-tTG IgG EIA Cat. Nr K160; Anti-tTG IgA EIA Cat. Nr K161	**DE/CA59/IVD/13/41**
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	**DE/CA59/IVD/13/40**
6.	IMMUNOGLOBULIN E – TOTAL	K200	Total IgE EIA Cat. Nr K200	**DE/CA59/IVD/13/39**
7.	THYROID STIMULATING HORMONE	K201 K201A	TSH EIA Cat. Nr K201; TSH Plus EIA Cat. Nr K201A	**DE/CA59/IVD/13/38**
8.	LUTEINISING HORMONE	K202	LH EIA Cat. Nr K202	**DE/CA59/IVD/13/37**
9.	FOLLICLE STIMULATING HORMONE	K203	FSH EIA Cat. Nr K203	**DE/CA59/IVD/13/36**
10.	HUMAN GROWTH HORMONE	K204	GH EIA Cat. Nr K204	**DE/CA59/IVD/13/35**
11.	HUMAN CHORIONIC GONADOTROPIN TOTAL	K205	HCG EIA Cat. Nr K205	**DE/CA59/IVD/13/34**
12.	PROLACTIN	K206	Prolactin EIA Cat. Nr K206	**DE/CA59/IVD/13/33**
13.	PROGESTERONE	K207 K207S	Progesterone EIA Cat. Nr K207 ; Salivary Progesterone EIA	**DE/CA59/IVD/13/32**
14.	ESTRADIOL	K208	Estradiol EIA Cat. Nr K208	**DE/CA59/IVD/13/31**
15.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K209 K209S	Testosterone EIA Cat. Nr K209 ; Salivary Testosterone EIA	**DE/CA59/IVD/13/30**
16.	CORTISOL	K210 K210S	Cortisol EIA Cat. Nr K210 ; Salivary Cortisol EIA	**DE/CA59/IVD/13/29**
17.	TRIIODOTHYRONINE	K211	T3 EIA Cat. Nr K211	**DE/CA59/IVD/13/28**
18.	THYROXINE	K212	T4 EIA Cat. Nr K212	**DE/CA59/IVD/13/27**
19.	FREE TRIIODOTHYRONINE	K213	Free T3 EIA Cat. Nr K213	**DE/CA59/IVD/13/26**
20.	FREE THYROXINE	K214	Free T4 EIA Cat. Nr K214	**DE/CA59/IVD/13/25**
21.	DEHYDRO-EPIANDROSTERONE SULPHATE (INCL. DHEA)	K215	DHEA-S EIA Cat. Nr K215	**DE/CA59/IVD/13/24**
22.	17 OH PROGESTERONE	K217	17-OH-Progesterone EIA Cat. Nr K217	**DE/CA59/IVD/13/22**
23.	CANCER ANTIGEN 125	K222	CA 125 EIA Cat. Nr K222	**DE/CA59/IVD/13/23**
24.	CANCER ANTIGEN 19-9	K223	CA 19.9 EIA Cat. Nr K223	**DE/CA59/IVD/13/21**
25.	CARCINOEMBRYONIC ANTIGEN	K224	CEA EIA Cat. Nr K224	**DE/CA59/IVD/13/20**

The above-mentioned medical products are marked with the CE symbol.
Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.

Polmed.de

Vertretung und Repräsentanz

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVD/Xema/01/2022

The following medical devices can be placed on the market in the Federal Republic of Germany, in the member states of the European Economic Community (EEC) and in the other contract states of the agreement about the European Economic Area.

Die folgenden Medizinprodukte in der Bundesrepublik Deutschland, in den Mitgliedsstaaten der Europäischen Wirtschaftsgemeinschaft (EG) und in den Vertragsstaaten der EG in den Verkehr gebracht werden dürfen.

	Nomenclature term Nomenklaturbezeichnung	Catalog No. Katalog-Nr.	Name of device Produktbezeichnung	DMIDS Registration number Registriernummer
26.	ALPHAFETOPROTEIN	K225	AFP EIA Cat. Nr K225	DE/CA59/IVD/13/19
27.	CANCER ANTIGEN 15-3	K226	M12 (CA 15.3) EIA Cat. NrK226	DE/CA59/IVD/13/18
28.	OTHER CANCER ANTIGENS	K227 K228	MUCI1 M22 EIA Cat. Nr K227; MUCI1 M20 EIA Cat. Nr K228	DE/CA59/IVD/13/17
29.	OTHER OTHER TUMOUR MARKERS	K232	Thyroglobulin EIA Cat. Nr K232	DE/CA59/IVD/13/16
30.	ß HUMAN CHORIONIC GONADOTROPIN (INCL. SUBUNIT)	K235	Free beta HCG EIA Cat. Nr K235	DE/CA59/IVD/13/15
31.	PREGNANCY ASSOCIATED PLASMA PROTEIN - A (DOWNS)	K238	PAPP-A EIA Cat. Nr K238	DE/CA59/IVD/13/14
32.	OTHER OTHER PLASMA PROTEINS	K240	Alveomucin EIA Cat. Nr K240	DE/CA59/IVD/13/13
33.	C-REACTIVE PROTEIN	K250	CRP EIA Cat. Nr K250	DE/CA59/IVD/13/12
34.	SEX HORMONE BINDING GLOBULIN	K268	SHBG EIA Cat. Nr K268	DE/CA59/IVD/13/11
35.	TROPONIN (T + I)	K291	Troponin I EIA Cat. Nr K291	DE/CA59/IVD/13/10
36.	IMMUNOGLOBULIN G	K271	Total IgG EIA Cat. Nr K271	DE/CA59/IVD/13/9
37.	IMMUNOGLOBULIN G SUBCLASS REAGENTS	K272 K274	IgG2 EIA Cat. Nr K272; IgG4 EIA Cat. Nr K274	DE/CA59/IVD/13/8
38.	IMMUNOGLOBULIN A	K275	Total IgA EIA Cat. Nr K275	DE/CA59/IVD/13/7
39.	IMMUNOGLOBULIN M	K277	Total IgM EIA Cat. Nr K277	DE/CA59/IVD/13/6
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	DE/CA59/IVD/13/5
41.	HORMONE CONTROLS	KQ21	HormoQon immunoassay control set Cat. Nr KQ21	DE/CA59/IVD/13/4
42.	TUMOUR MARKER CONTROLS	KQ22	OmaQon immunoassay control set Cat. Nr KQ22	DE/CA59/IVD/13/3
43.	CYFRA 21-1	K236	CYFRA 21-1 EIA	DE/CA59/IVD/13/45
44.	CANCER ANTIGEN 72-4	K244	CA 72-4 EIA	DE/CA59/IVD/13/46
45.	NEONATAL THYROID STIMULATING HORMONE	K201N	TSH-Neo EIA	DE/CA59/IVD/13/47
46.	ESTRIOL	K218	Free Estriol EIA	DE/CA59/IVD/13/48
47.	IMMUNOGLOBULIN E - MONOTEST/MONORESULT - MULTI AG	K200S	Specific IgE EIA	DE/CA59/IVD/13/49
48.	KAPPA AND LAMBDA CHAIN	K279K K279L	Free kappa Igg light chain EIA, Free lambda Igg light chain EIA	DE/CA59/IVD/13/50
49.	TRYPSIN NEONATAL	K242	Neonatal IRT EIA Cat. Nr K242	DE/CA59/IVD/13/51
50.	NEURON SPECIFIC ENOLASE	K234	NSE EIA Cat. Nr K234	DE/CA59/IVD/13/52

The above-mentioned medical products are marked with the CE symbol.
Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.

Polmed.de

Vertretung und Repräsentanz

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVD/Xema/01/2022

The following medical devices can be placed on the market in the Federal Republic of Germany, in the member states of the European Economic Community (EEC) and in the other contract states of the agreement about the European Economic Area.

Die folgenden Medizinprodukte in der Bundesrepublik Deutschland, in den Mitgliedsstaaten der Europäischen Wirtschaftsgemeinschaft (EG) und in den Vertragsstaaten der EG in den Verkehr gebracht werden dürfen.

	Nomenclature term Nomenklaturbezeichnung	Catalog No. Katalog-Nr.	Name of device Produktbezeichnung	DMIDS Registration number Registriernummer
50.	NEURON SPECIFIC ENOLASE	K234	NSE EIA Cat. Nr K234	DE/CA59/IVD/13/52
51.	OTHER OTHER TUMOUR MARKERS	K239	HE – 4 EIA Cat. Nr K239	DE/CA59/IVD/13/53
52.	HSV IgG	K104	HSV ½ IgG EIA (Cat. Nr K104)	DE/CA59/IVD/13/67
53.	HSV IgM	K104M	HSV ½ IgM EIA (Cat. Nr K104M)	DE/CA59/IVD/13/66
54.	MYCOPLASMA ANTIBODY ASSAYS	K106	Mycoplasma IgG EIA (Cat. Nr K106)	DE/CA59/IVD/13/65
55.	SYPHILIS ANTIBODY ASSAYS TOTAL	K111	Treponema pallidum Total Ab EIA (Cat. Nr K111)	DE/CA59/IVD/13/64
56.	SYPHILIS ANTIBODY IGG	K111G	Treponema pallidum IgG EIA (Cat. Nr K111G)	DE/CA59/IVD/13/63
57.	SYPHILIS ANTIBODY IGM	K111M	Treponema pallidum IgM EIA (Cat. Nr K111M)	DE/CA59/IVD/13/62
58.	H. PYLORI ANTIBODY ASSAYS	K119	H.pylori IgG EIA (Cat. Nr K119)	DE/CA59/IVD/13/61
59.	H. PYLORI ANTIBODY ASSAYS	K119M	H.pylori IgM EIA (Cat. Nr K119M)	DE/CA59/IVD/13/60
60.	ASPERGILLUS	K121	Aspergillus IgG EIA (Cat. Nr K121)	DE/CA59/IVD/13/59
61.	OTHER OTHER BACTERIOLOGY IMMUNOASSAY	K126	Ureaplasma IgG EIA (Cat. Nr K126)	DE/CA59/IVD/13/58
62.	GIARDIA LAMBLIA	K171 K171X	Giardia lamblia Total Ab EIA (Cat. Nr 171) Giardia lamblia IgG/IgM/IgA EIA (Cat. No. K171X)	DE/CA59/IVD/13/57Ä1
63.	OTHER TUMOUR MARKER RAPID TESTS	X22OV	XEMAtestOvaScreen (Cat. Nr X22OV)	DE/CA59/IVD/13/56
64.	OTHER TUMOUR MARKER RAPID TESTS	X222	XEMAtestCA125 (Cat. Nr X222)	DE/CA59/IVD/13/55
65.	OTHER TUMOUR MARKER RAPID TESTS	X239	XEMAtestHE4 (Cat. Nr X239)	DE/CA59/IVD/13/54
66.	IMMUNOGLOBULIN A IgA	K276	SECRETORY IgA (sIgA) EIA (Cat. No. K276)	DE/CA59/IVD/13/68
67.	ECHINOCOCCUS	K175	Cestodes IgG EIA (Cat. No. K175)	DE/CA59/IVD/13/72E
68.	DISTOMATOSIS	K176	Fasciola IgG EIA (Cat. No. K176)	DE/CA59/IVD/13/71E
69.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K219	Free Testosterone EIA (Cat. No. K219)	DE/CA59/IVD/13/70E
70.	HUMAN PLACENTAL LACTOGEN HPL	K246	Human Placental Lactogen EIA (Cat. No. K246)	DE/CA59/IVD/13/69E
71.	CANCER ANTIGEN 242	K243	CA 242 EIA (Cat. No. K243)	DE/CA59/IVD/13/73
72.	INSULIN	K267N	Insulin EIA (Cat. No. K267N)	DE/CA59/IVD/13/77
73.	C-PEPTIDE	K267C	C-peptide EIA(Cat. No. K267C)	DE/CA59/IVD/13/76
74.	OTHER PREGNANCY TESTING HORMONES	K245	AMH EIA (Cat. No. K245)	DE/CA59/IVD/13/75
75.	SQUAMOUS CELL CARCINOMA ANTIGEN	K237	SCC(A) EIA (Cat. No. K237)	DE/CA59/IVD/13/74
76.	ASPERGILLUS	K021	GalM Ag EIA (Cat. No. K021)	DE/CA59/IVD/13/78

The above-mentioned medical products are marked with the CE symbol.
Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.

Represented in the EC by:

Polmed.de Beata Rozwadowska
Fichtenstr. 12A, 90763 Fürth, Germany
email: info@polmed.de
Tel: +49 911 93163967

Beata Rozwadowska * Polmed.de * Fichtenstr. 12a, 90763 Fürth, Germany

Date: **May 26, 2022**

Polmed.de

Valid with the Extract from the database www.dimdi.de (German Medical Device Information and Database System (DMIDS))
Gilt nur mit :Auszug aus der Datenbank www.dimdi.de (Deutsches Medizinprodukte-Informations- und Datenbanksystem (DMIDS))

ООО «ХЕМА»
105264, г. Москва, ул. 9-я Парковая, д. 48, 5 эт.
+7 (495) 510-57-07
8 800 505-23-45
sale@xema.ru
www.xema-medica.com

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

DNV

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

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

FINAS
Finnish Accreditation Service
S001 (EN ISO/IEC 17021-1)

Kimmo Haarala
Management Representative

Certificate no.: 282710-2019-AQ-MCW-FINAS
Place and date: Espoo, 14 February 2022

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.