

Certificate

Of Marketing Authorization of Medical Product

Nr. **AR/IVMD/Xema/01/2020**

Issued on the basis of the Declaration of conformity and registration taking into account Article 10 of Directive 98/79/EC on In Vitro Diagnostic Medical Devices and Medical Devices Act (MPG) § § 5,25,29,30

Ausgestellt auf Grund der Konformitätserklärung und Registrierung unter Berücksichtigung der Richtlinie 98/97/EG Artikel 10 über In-vitro-Diagnostika und Medizinproduktgesetz (MPG) §§ 5,25,29,30

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 Module:
Konformitätsmodul

Module A (EC Declaration of Conformity)
(Annex III, except point 6, Directive 98/79/EC)
Modul A (EG-Konformitätserklärung)
(Anhang III, außer Nummer 6, Richtlinie 98/79 / EG)

Lead Competent Authority:
Zuständige Behörde

DIMDI – German Institute of Medical Documentation and Information
DIMDI – Deutsches Institut für Medizinische Dokumentation und Information

Product Registration Ref. No.:
(Per Article 10, Directive 98/79/EC)
Produkt Registrationsnummer
(Gemäß Artikel 10 der Richtlinie 98/79 / EG)

See annex to the Certificate
Siehe Anhang zum Zertifikat

Date of issue: 2020-01-01
Das Ausstellungsdatum

Valid to : 2022-05-25
Gültig bis

Represented in the EC by Polmed.de
Steinacker 5, 73773 Aichwald, Germany
email: info@polmed.de
tel: +49 711 52853279



Polmed.de

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVMD/Xema/01/2020

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 | DIMDI Registration number Registriernummer |
|-----|---|------------------------------------|--|---|
| 1. | THYROID PEROXIDASE (INCL. MICROSOMAL) ANTIBODIES | K131 | aTPO EIA Cat. Nr K131 | DE/CA37/IVD/13/44 |
| 2. | THYROGLOBULIN AUTOANTIBODIES | K132 | aTG EIA Cat. Nr K132 | DE/CA37/IVD/13/43 |
| 3. | MPO ANCA | K133 | aMPO EIA Cat. Nr K133 | DE/CA37/IVD/13/42 |
| 4. | TISSUE TRANSGLUTAMINASE ANTIBODIES | K160 K161 | Anti-tTG IgG EIA Cat. Nr K160; Anti-tTG IgA EIA Cat. Nr K161 | DE/CA37/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/CA37/IVD/13/40 |
| 6. | IMMUNOGLOBULIN E – TOTAL | K200 | Total IgE EIA Cat. Nr K200 | DE/CA37/IVD/13/39 |
| 7. | THYROID STIMULATING HORMONE | K201 K201A | TSH EIA Cat. Nr K201; TSH Plus EIA Cat. Nr K201A | DE/CA37/IVD/13/38 |
| 8. | LUTEINISING HORMONE | K202 | LH EIA Cat. Nr K202 | DE/CA37/IVD/13/37 |
| 9. | FOLLICLE STIMULATING HORMONE | K203 | FSH EIA Cat. Nr K203 | DE/CA37/IVD/13/36 |
| 10. | HUMAN GROWTH HORMONE | K204 | GH EIA Cat. Nr K204 | DE/CA37/IVD/13/35 |
| 11. | HUMAN CHORIONIC GONADOTROPIN TOTAL | K205 | HCG EIA Cat. Nr K205 | DE/CA37/IVD/13/34 |
| 12. | PROLACTIN | K206 | Prolactin EIA Cat. Nr K206 | DE/CA37/IVD/13/33 |
| 13. | PROGESTERONE | K207 K207S | Progesterone EIA Cat. Nr K207 ; Salivary Progesterone EIA | DE/CA37/IVD/13/32 |
| 14. | ESTRADIOL | K208 | Estradiol EIA Cat. Nr K208 | DE/CA37/IVD/13/31 |
| 15. | TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE) | K209 K209S | Testosterone EIA Cat. Nr K209 ; Salivary Testosterone EIA | DE/CA37/IVD/13/30 |
| 16. | CORTISOL | K210 K210S | Cortisol EIA Cat. Nr K210 ; Salivary Cortisol EIA | DE/CA37/IVD/13/29 |
| 17. | TRIIODOTHYRONINE | K211 | T3 EIA Cat. Nr K211 | DE/CA37/IVD/13/28 |
| 18. | THYROXINE | K212 | T4 EIA Cat. Nr K212 | DE/CA37/IVD/13/27 |
| 19. | FREE TRIIODOTHYRONINE | K213 | Free T3 EIA Cat. Nr K213 | DE/CA37/IVD/13/26 |
| 20. | FREE THYROXINE | K214 | Free T4 EIA Cat. Nr K214 | DE/CA37/IVD/13/25 |
| 21. | DEHYDRO-EPIANDROSTERONE SULPHATE (INCL. DHEA) | K215 | DHEA-S EIA Cat. Nr K215 | DE/CA37/IVD/13/24 |
| 22. | 17 OH PROGESTERONE | K217 | 17-OH-Progesterone EIA Cat. Nr K217 | DE/CA37/IVD/13/22 |
| 23. | CANCER ANTIGEN 125 | K222 | CA 125 EIA Cat. Nr K222 | DE/CA37/IVD/13/23 |
| 24. | CANCER ANTIGEN 19-9 | K223 | CA 19.9 EIA Cat. Nr K223 | DE/CA37/IVD/13/21 |
| 25. | CARCINOEMBRYONIC ANTIGEN | K224 | CEA EIA Cat. Nr K224 | DE/CA37/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.

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVMD/Xema/01/2020

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 | DIMDI Registration number Registriernummer |
|-----|---|------------------------------------|---|---|
| 26. | ALPHAFETOPROTEIN | K225 | AFP EIA Cat. Nr K225 | DE/CA37/IVD/13/19 |
| 27. | CANCER ANTIGEN 15-3 | K226 | M12 (CA 15.3) EIA Cat. NrK226 | DE/CA37/IVD/13/18 |
| 28. | OTHER CANCER ANTIGENS | K227 K228 | MUC11 M22 EIA Cat. Nr K227; MUC11 M20 EIA Cat. Nr K228 | DE/CA37/IVD/13/17 |
| 29. | OTHER OTHER TUMOUR MARKERS | K232 | Thyroglobulin EIA Cat. Nr K232 | DE/CA37/IVD/13/16 |
| 30. | β HUMAN CHORIONIC GONADOTROPIN (INCL. SUBUNIT) | K235 | Free beta HCG EIA Cat. Nr K235 | DE/CA37/IVD/13/15 |
| 31. | PREGNANCY ASSOCIATED PLASMA PROTEIN - A (DOWNS) | K238 | PAPP-A EIA Cat. Nr K238 | DE/CA37/IVD/13/14 |
| 32. | OTHER OTHER PLASMA PROTEINS | K240 | Alveomucin EIA Cat. Nr K240 | DE/CA37/IVD/13/13 |
| 33. | C-REACTIVE PROTEIN | K250 | CRP EIA Cat. Nr K250 | DE/CA37/IVD/13/12 |
| 34. | SEX HORMONE BINDING GLOBULIN | K268 | SHBG EIA Cat. Nr K268 | DE/CA37/IVD/13/11 |
| 35. | TROPONIN (T + I) | K291 | Troponin I EIA Cat. Nr K291 | DE/CA37/IVD/13/10 |
| 36. | IMMUNOGLOBULIN G | K271 | Total IgG EIA Cat. Nr K271 | DE/CA37/IVD/13/9 |
| 37. | IMMUNOGLOBULIN G SUBCLASS REAGENTS | K272 K274 | IgG2 EIA Cat. Nr K272; IgG4 EIA Cat. Nr K274 | DE/CA37/IVD/13/8 |
| 38. | IMMUNOGLOBULIN A | K275 | Total IgA EIA Cat. Nr K275 | DE/CA37/IVD/13/7 |
| 39. | IMMUNOGLOBULIN M | K277 | Total IgM EIA Cat. Nr K277 | DE/CA37/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/CA37/IVD/13/5 |
| 41. | HORMONE CONTROLS | KQ21 | HormoQon immunoassay control set Cat. Nr KQ21 | DE/CA37/IVD/13/4 |
| 42. | TUMOUR MARKER CONTROLS | KQ22 | OmaQon immunoassay control set Cat. Nr KQ22 | DE/CA37/IVD/13/3 |
| 43. | CYFRA 21-1 | K236 | CYFRA 21-1 EIA | DE/CA37/IVD/13/45 |
| 44. | CANCER ANTIGEN 72-4 | K244 | CA 72-4 EIA | DE/CA37/IVD/13/46 |
| 45. | NEONATAL THYROID STIMULATING HORMONE | K201N | TSH-Neo EIA | DE/CA37/IVD/13/47 |
| 46. | ESTRIOL | K218 | Free Estriol EIA | DE/CA37/IVD/13/48 |
| 47. | IMMUNOGLOBULIN E - MONOTEST/MONORESULT - MULTI AG | K200S | Specific IgE EIA | DE/CA37/IVD/13/49 |
| 48. | KAPPA AND LAMBDA CHAIN | K279K K279L | Free kappa Igg light chain EIA, Free lambda Igg light chain EIA | DE/CA37/IVD/13/50 |
| 49. | TRYPsin NEONATAL | K242 | Neonatal IRT EIA Cat. Nr K242 | DE/CA37/IVD/13/51 |
| 50. | NEURON SPECIFIC ENOLASE | K234 | NSE EIA Cat. Nr K234 | DE/CA37/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.

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVMD/Xema/01/2020

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.

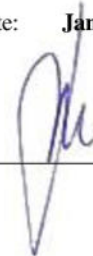
| | Nomenclature term Nomenklaturbezeichnung | Catalog No. Katalog-Nr. | Name of device Produktbezeichnung | DIMDI Registration number Registriernummer |
|-----|---|----------------------------|--|--|
| 50. | NEURON SPECIFIC ENOLASE | K234 | NSE EIA Cat. Nr K234 | DE/CA37/IVD/13/52 |
| 51. | OTHER OTHER TUMOUR MARKERS | K239 | HE – 4 EIA Cat. Nr K239 | DE/CA37/IVD/13/53 |
| 52. | HSV IgG | K104 | HSV ½ IgG EIA (Cat. Nr K104) | DE/CA37/IVD/13/67 |
| 53. | HSV IgM | K104M | HSV ½ IgM EIA (Cat. Nr K104M) | DE/CA37/IVD/13/66 |
| 54. | MYCOPLASMA ANTIBODY ASSAYS | K106 | Mycoplasma IgG EIA (Cat. Nr K106) | DE/CA37/IVD/13/65 |
| 55. | SYPHILIS ANTIBODY ASSAYS TOTAL | K111 | Treponema pallidum Total Ab EIA (Cat. Nr K111) | DE/CA37/IVD/13/64 |
| 56. | SYPHILIS ANTIBODY IGG | K111G | Treponema pallidum IgG EIA (Cat. Nr K111G) | DE/CA37/IVD/13/63 |
| 57. | SYPHILIS ANTIBODY IGM | K111M | Treponema pallidum IgM EIA (Cat. Nr K111M) | DE/CA37/IVD/13/62 |
| 58. | H. PYLORI ANTIBODY ASSAYS | K119 | H.pylori IgG EIA (Cat. Nr K119) | DE/CA37/IVD/13/61 |
| 59. | H. PYLORI ANTIBODY ASSAYS | K119M | H.pylori IgM EIA (Cat. Nr K119M) | DE/CA37/IVD/13/60 |
| 60. | ASPERGILLUS | K121 | Aspergillus IgG EIA (Cat. Nr K121) | DE/CA37/IVD/13/59 |
| 61. | OTHER OTHER BACTERIOLOGY IMMUNOASSAY | K126 | Ureaplasma IgG EIA (Cat. Nr K126) | DE/CA37/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/CA37/IVD/13/57Ä1 |
| 63. | OTHER TUMOUR MARKER RAPID TESTS | X220V | XEMAtestOvaScreen (Cat. Nr X220V) | DE/CA37/IVD/13/56 |
| 64. | OTHER TUMOUR MARKER RAPID TESTS | X222 | XEMAtestCA125 (Cat. Nr X222) | DE/CA37/IVD/13/55 |
| 65. | OTHER TUMOUR MARKER RAPID TESTS | X239 | XEMAtestHE4 (Cat. Nr X239) | DE/CA37/IVD/13/54 |
| 66. | IMMUNOGLOBULIN A IgA | K276 | SECRETORY IgA (sIgA) EIA (Cat. No. K276) | DE/CA37/IVD/13/68 |
| 67. | ECHINOCOCCUS | K175 | Cestodes IgG EIA (Cat. No. K175) | DE/CA37/IVD/13/72E |
| 68. | DISTOMATOSIS | K176 | Fasciola IgG EIA (Cat. No. K176) | DE/CA37/IVD/13/71E |
| 69. | TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE) | K219 | Free Testosterone EIA (Cat. No. K219) | DE/CA37/IVD/13/70E |
| 70. | HUMAN PLACENTAL LACTOGEN HPL | K246 | Human Placental Lactogen EIA (Cat. No. K246) | DE/CA37/IVD/13/69E |
| 71. | CANCER ANTIGEN 242 | K243 | CA 242 EIA (Cat. No. K243) | DE/CA37/IVD/13/73 |
| 72. | INSULIN | K267N | Insulin EIA (Cat. No. K267N) | DE/CA37/IVD/13/77 |
| 73. | C-PEPTIDE | K267C | C-peptide EIA (Cat. No. K267C) | DE/CA37/IVD/13/76 |
| 74. | OTHER PREGNANCY TESTING HORMONES | K245 | AMH EIA (Cat. No. K245) | DE/CA37/IVD/13/75 |
| 75. | SQUAMOUS CELL CARCINOMA ANTIGEN | K237 | SCC(A) EIA (Cat. No. K237) | DE/CA37/IVD/13/74 |
| 76. | ASPERGILLUS | K021 | GalM Ag EIA (Cat. No. K021) | DE/CA37/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
 Steinacker 5, 73773 Aichwald, Germany
 email: info@polmed.de
 tel: +49 711 52853279



Date: January 01, 2020



Polmed.de