

# 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**  
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Polmed.de

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|     | <b>Nomenclature term<br/>Nomenklaturbezeichnung</b> | <b>Catalog No.<br/>Katalog-Nr.</b> | <b>Name of device Produktbezeichnung</b>   | <b>DIMDI<br/>Registration number<br/>Registriernummer</b> |
|-----|---|------------------------------------|--|---|
| 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<br>K161                       | Anti-tTG IgG EIA Cat. Nr K160;<br>Anti-tTG IgA EIA Cat. Nr K161  | DE/CA37/IVD/13/41   |
| 5.  | GLIADIN ANTIBODIES                                  | K180<br>K181<br>K182A<br>K182G     | Gliadin IgG EIA Cat. Nr K180;<br>Gliadin IgA EIA Cat. Nr K181 ;<br>Deamidated Gliadin IgA EIA,<br>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<br>K201A                      | TSH EIA Cat. Nr K201;<br>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<br>K207S                      | Progesterone EIA Cat. Nr K207 ;<br>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<br>K209S                      | Testosterone EIA Cat. Nr K209 ;<br>Salivary Testosterone EIA   | DE/CA37/IVD/13/30   |
| 16. | CORTISOL  | K210<br>K210S                      | Cortisol EIA Cat. Nr K210 ;<br>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<br>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.

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|-----|---|------------------------------------|---|---|
| 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<br>K228                       | MUC1 M22 EIA Cat. Nr K227;<br>MUC1 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<br>K274                       | IgG2 EIA Cat. Nr K272;<br>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<br>KQ14<br>KQ15               | AutoQon AT immunoassay control set Cat. Nr KQ13;<br>AutoQon ANA/ENA immunoassay control set Cat. Nr KQ14;<br>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<br>K279L                     | Free kappa Igg light chain EIA,<br>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   |

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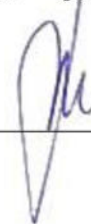
|     | Nomenclature term<br>Nomenklaturbezeichnung       | Catalog No.<br>Katalog-Nr. | Name of device Produktbezeichnung  | DIMDI<br>Registration number<br>Registriernummer |
|-----|---|----------------------------|--|--|
| 50. | NEURON SPECIFIC ENOLASE                           | K234                       | 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<br>K171X              | Giardia lamblia Total Ab EIA (Cat. Nr 171)<br>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                                |

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Date: January 01, 2020



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