

EC Declaration of Conformity

According to Directive 98/79/EC, on in vitro diagnostic medical devices

Ref. No.: 220324-J01

Maker
(Name, Address) **Getein Biotech, Inc.**
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Authorized Representative
(Name, Address) **CMC Medical Devices & Drugs S.L.**
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain

Product Name

Medical device

1. 5'-NT Reagent Kit (POD Method)
2. ACE Reagent Kit (FAPGG Substrate Method)
3. ADA Reagent Kit (POD Method)
4. ALB Reagent Kit (BCG Colorimetric Method)
5. ALP Reagent Kit (NPP Substrate-AMP Buffer Method)
6. ALT Reagent Kit (Alanine Substrate Method)
7. AMY Reagent Kit (EPS Substrate Method)
8. ApoA1 Reagent Kit (Immunoturbidimetric Method)
9. ApoB Reagent Kit (Immunoturbidimetric Method)
10. ApoE Reagent Kit (Immunoturbidimetric Method)
11. ASO Reagent Kit (Immunoturbidimetric Method)
12. AST Reagent Kit (Asparaginic Acid Substrate Method)
13. Urea Reagent Kit-1(Urease-GLDH Kinetic method)
14. Urea Reagent Kit-2(Urease-GLDH Kinetic method)
15. C3 Reagent Kit (Immunoturbidimetric Method)
16. C4 Reagent Kit (Immunoturbidimetric Method)
17. Ca Reagent Kit (Arsenazo III Colorimetric Method)
18. CCP Reagent Kit (Immunoturbidimetric Method)
19. CG Reagent Kit (Immunoturbidimetric Method)
20. CHE Reagent Kit (Butylthiocholine Kinetic method)
21. CK-MB Reagent Kit (immunoinhibition method)
22. CK Reagent Kit (Phosphocreatine Substrate method)
23. Cl Reagent Kit (Thiocyanate Colorimetric Method)
24. CO2 Reagent Kit (PEPC Method)
25. CRE-E Reagent Kit (Enzymatic Method)
26. CRP Reagent Kit (Immunoturbidimetric Method)
27. CSF Reagent Kit (Pyrogallol red Colorimetric Method)
28. CYS-C Reagent Kit (Latex-enhanced Immunoturbidimetric Method)

29. CRP Reagent Kit (Latex-enhanced Immunoturbidimetric Method)
30. D3-H Reagent Kit (Kinetic Method)
31. DB Reagent Kit (Chemical Oxidation Method)
32. D-Dimer Reagent Kit (Immunoturbidimetric Method)
33. Fe Reagent Kit (Ferrozine Chromogenic Method)
34. FMN Reagent Kit (NBT Reductive Method)
35. GA Reagent Kit (POD Method)
36. GGT Reagent Kit (GCANA substrate Method)
37. GLDH Reagent Kit (Kinetic Method)
38. GLU-HK Reagent Kit (Hexokinase Enzymatic Method)
39. GLU-OX Reagent Kit-2 (GOD-POD Method)
40. GLU-OX Reagent Kit-1 (GOD-POD Method)
41. GPDA Reagent Kit (Enzyme Kinetic Method)
42. HbA1c Reagent Kit (Immunoturbidimetric Method)
43. HBDH Reagent Kit (Kinetic Method)
44. HCY Reagent Kit (Enzymatic Cycling Method)
45. HDL-C Reagent Kit (Direct Colorimetric Method)
46. IgA Reagent Kit (Immunoturbidimetric Method)
47. IgG Reagent Kit (Immunoturbidimetric Method)
48. IgM Reagent Kit (Immunoturbidimetric Method)
49. K Reagent Kit (Enzymatic Method)
50. LAC Reagent Kit (LO - POD Enzymatic-Colorimetric Method)
51. LAP Reagent Kit (L-leucyl-nitroaniline substrate Method)
52. LDH1 Reagent Kit (L-P Method)
53. LDH Reagent Kit (Lactate Substrate Method)
54. LDL-C Reagent Kit-1(Direct Method)
55. LDL-C Reagent Kit-2(Direct Method)
56. Lp(a) Reagent Kit(Immunoturbidimetric Method)
57. LPS Reagent Kit (Enzyme Colorimetric Method)
58. MALB Reagent Kit (Immunoturbidimetric Method)
59. MAO Reagent Kit (Colorimetric method)
60. Mg Reagent Kit (Colorimetric Method)
61. NAG Reagent Kit (MNP-GLcNAc Substrate Method)
62. NA Reagent Kit (Enzymatic Method)
63. NEFA Reagent Kit (Enzymatic Colorimetric Method)
64. PA Reagent Kit (Immunoturbidimetric Method)
65. PGI Reagent Kit (Immunoturbidimetric Method)
66. PGII Reagent Kit (Immunoturbidimetric Method)
67. P Reagent Kit (Phosphomolybdate Method)
68. RBP Reagent Kit (Immunoturbidimetric Method)
69. RF Reagent Kit (Immunoturbidimetric Method)
70. SA Reagent Kit (Enzymatic Method)

71. TBA Reagent Kit (Enzymatic Cycling Method)
72. TB Reagent Kit (Chemical Oxidation Method)
73. TCH Reagent Kit-1 (CHOD-PAP Enzymatic-Colorimetric Method)
74. TCH Reagent Kit-2 (CHOD-PAP Enzymatic-Colorimetric Method)
75. TG Reagent Kit-1 (GPO-PAP Enzymatic-Colorimetric Method)
76. TG Reagent Kit-2 (GPO-PAP Enzymatic-Colorimetric Method)
77. TP Reagent Kit (Biuret Colorimetric Method)
78. UA Reagent Kit-1 (Uricase Method)
79. UA Reagent Kit-2 (Uricase Method)
80. UIBC Reagent Kit (Ferrozine Chromogenic Method)
81. Beta2-MG Reagent Kit (Immunoturbidimetric Method)
82. Composite Calibrator serum
83. Composite quality control serum
84. Lipid compound calibrator
85. Lipid compound control
86. hs-CRP Reagent Kit (Immunoturbidimetric Method)
87. AFU Reagent Kit (CNPf Substrate Method)
88. Lp-PLA2 Reagent Kit (14-NPC Substrate Method)
89. TRF Reagent kit (Immunoturbidimetric Method)
90. AMM Reagent kit (GLDH Kinetic method)
91. CK-MB Reagent kit (Immunoturbidimetric Method)
92. Myo Reagent kit (Immunoturbidimetric Method)
93. GR Reagent Kit (Glutathione Substrate Method)
94. Fer Reagent kit (Immunoturbidimetric Method)
95. Special Protein Control
96. Dengue IgG/IgM Antibody Fast Test Kit (Immunofluorescence Assay)
97. H. pylori Antibody Fast Test Kit (Immunofluorescence Assay)
98. FluA/FluB/SARS-CoV-2 Antigen Fast Test Kit (Immunofluorescence Assay)
99. Malaria P.f/P.v Ag Rapid Test (Colloidal Gold Assay)
100. Malaria P.f/Pan Ag Rapid Test (Colloidal Gold Assay)
101. Malaria P.f Ag Rapid Test (Colloidal Gold Assay)



Classification

Others

Applicable

EN 13612:2002

EN ISO 14971:2019

EN ISO15223-1:2016

coordination

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

standards

EN ISO 23640:2015

EN ISO 13485:2016

ISO 780:2015

Signatory representative declares herein the above-mentioned devices meet the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex III.

This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by BSI Group The Netherlands B. V.. The manufacturer is exclusively responsible for the declaration of conformity.

General Manager Enben Su



Nanjing, March 16, 2022

Nanjing, March 16, 2022

(place and date of issue)



(name and signature of equivalent

marking of authorized person)

