



## EU DECLARATION OF CONFORMITY

**MANUFACTURER:** VITROSENS BİYOTEKNOLOJİ ANONİM ŞİRKETİ

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In accordance with the in Vitro Diagnostic Medical Device Directive 98/79/EC according to Annex III (excluding section 6) for the products described below, we declare that their requirements have been done and we take the responsibility.

**PRODUCT:**

Syphilis Ab Rapid Test Kit  
Chikungunya IgM Rapid Test Kit  
Dengue IgG/IgM + NS1 Combo Rapid Test Kit  
Dengue IgG/IgM/NS1 Rapid Test Kit  
Dengue NS1 Rapid Test Kit  
FOB Rapid Test Kit  
H.Pylori Ag Rapid Test Kit  
Influenza A/B Rapid Test Kit  
K2 Rapid Test Kit  
KET Rapid Test Kit  
Malaria P.f. Rapid Test Kit  
Malaria P.f. / Pan Rapid Test Kit  
Malaria P.f. / P.v. Rapid Test Kit  
Rotavirus Rapid Test Kit  
Rota + Adeno Virus Combo Rapid Test Kit  
Salmonella Typhi Rapid Test Kit  
Typhoid IgG/IgM Rapid Test Kit  
H.Pylori Ab Rapid Test Kit  
Strep A Rapid Test Kit  
Tuberculosis IgG/IgM Rapid Test Kit  
Dengue IgG/IgM Rapid Test Kit  
Neisseria Gonorrhoeae Rapid Test Kit  
Adenovirus Rapid Test Kit  
Norovirus Rapid Test Kit  
Astrovirus Rapid Test Kit  
Zika IgM Rapid Test Kit  
AFP Rapid Test Kit  
CEA Rapid Test Kit  
PCT Rapid Test Kit

CRP Rapid Test Kit  
Troponin I Rapid Test Kit  
Myoglobin Rapid Test Kit  
CK-MB Rapid Test Kit  
Chikungunya IgG/IgM Rapid Test Kit  
H-FABP Rapid Test Kit  
NT-proBNP Rapid Test Kit  
Myo + CK-MB + Troponin I Combo Rapid Test Kit  
D-Dimer Rapid Test Kit  
cTnI + NT-proBNP + D-Dimer Combo Rapid Test Kit  
H-FABP + cTnI Combo Rapid Test Kit  
hCG Rapid Test Kit  
hCG Rapid Test Kit (Midstream)  
Ovulation LH Rapid Test Kit  
Sperm Rapid Test Kit  
Celiac Rapid Test Kit  
Vitamin-D Rapid Test Kit  
Mycoplasma Ab Rapid Test Kit  
RSV Rapid Test Kit  
Giardia Lamblia Rapid Test Kit  
Cryptosporidium Rapid Test Kit  
Entamoeba Rapid Test Kit  
FOB + Transferrin Combo Rapid Test Kit  
SARS-CoV-2 + Flu A/B + RSV Combo Rapid Test Kit  
Sickle Cell Rapid Test Kit  
Monkeypox Virus Ag Rapid Test Kit  
Monkeypox Virus Ab Rapid Test Kit  
Rota/Adeno Rapid Test Kit  
Ultra FOB Rapid Test Kit  
FLU A/B + RSV Combo Test Kit  
FLU A/B + RSV + ADV Combo Test Kit  
SARS-CoV-2 + Flu A/B + RSV+ ADV Combo Rapid Test Kit  
SARS-CoV-2 + RSV Combo Rapid Test Kit  
SARS-CoV-2 + FLUA/B + RSV + ADV + Mycoplasma Combo Rapid Test Kit  
Mycoplasma Ag Rapid Test Kit  
ADV Resp. Rapid Test Kit  
Rota/Adeno + Norovirus Combo Rapid Test Kit  
Vitamin B-12 Rapid Test Kit  
FSH Rapid Test Kit  
Cholera O1/O139 Rapid Test Kit  
C.difficile GDH Rapid Test Kit  
C.difficile Toxin A + B Combo Rapid Test Kit  
Rheumatoid factor (RF) Rapid Test Kit  
Rota + Adeno + Noro + Astrovirus Combo Rapid Test Kit  
Legionella pneumoniae Rapid Test Kit  
Rota + Adeno + Norovirus Combo Rapid Test Kit

Crypto + Giardia + Entamoeba Combo Rapid Test Kit  
RSV + ADV Resp. Combo Rapid Test Kit  
C.difficile GDH + Toxin A + Toxin B Combo Rapid Test Kit  
Ferritin Rapid Test Kit  
TSH Rapid Test Kit  
ADV + M. pneumoniae Combo Rapid Test Kit  
HSV-1 IgG/IgM Rapid Test Kit  
HSV-2 IgG/IgM Rapid Test Kit  
hCG + LH Combo Rapid Test Kit  
HEV IgM Rapid Test Kit  
UTI Rapid Strip Test  
Crypto + Giardia Combo Rapid Test Kit  
Enterovirus 71 IgM Rapid Test Kit  
Chlamydia + Gonorrhea Combo Rapid Test Kit  
Streptococcus pneumoniae Rapid Test Kit  
RSV/Adeno Rapid Test Kit  
Leishmania Ab Rapid Test Kit  
Trichomonas Vaginalis Rapid Test Kit  
Calprotectin Rapid Test Kit  
Lactoferrin Rapid Test Kit  
Transferrin Rapid Test Kit  
FOB + Transferrin + Calprotectin + Lactoferrin Combo Rapid Test Kit  
HPV Rapid Test Kit  
IGFBP-1 Rapid Test  
Total IgE Rapid Test Kit  
Enterovirus Ag Rapid Test Kit

**MODEL:** RapidFor™  
**CLASS:** In-Vitro Diagnostic (IVD) – Others  
**HARMONISED STANDARDS:**  
EN ISO 13485:2016  
EN ISO 9001:2015 (QMS)

This declaration of conformity is issued under the exclusive responsibility of the manufacturer.

**Place of issue:** İstanbul  
**Date of issue:** 27.04.2022

**Kağan Etki YÖRÜK**  
General Manager



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