VITROSENS
BIOTECHNOLOGY

CE

# EU DECLARATION OF CONFORMITY

**MANUFACTURER:** VITROSENS BİYOTEKNOLOJİ ANOMİM ŞİRKETİ

**ADDRESS:** Şerifali Mah. Şehit Sok. No:17/A, Ümraniye/İstanbul, Türkiye

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:** H.pylori Ag Rapid Test Kit
Strep A 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 Etka YÖRÜK**
**General Manager**

VITROSENS BİYOTEKNOLOJİ ANOMİM ŞİRKETİ
Şerifali Mah. Şehit Sok. No.17A Ümraniye / İST.
Sanayi V.D. 9251175360 Sic. No: 279270-5
vitrosens.com | info@vitrosens.com