

1.01 / Nome Commerciale

SELF-TEST HOTGEN ANTIGENE COVID-19 – soft pack- 1 Test

ART. COD. EG16GN35

1.02 / Imported by
Kimesta d.o.o.

1.03 / Origin
China

1.04 / CE Certification
Available upon request

1.05 / Inteded use
Self-diagnosis

1.06 / EU Regulation
Directive IVDD 98/79/CE

1.07 / Standards
EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14791:2012, EN ISO 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 3612:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN ISO 13641:2002, EN ISO 13975:2003, EN ISO 62366:2008

1.08 / REF n.
HGCG134S0101

1.09 / RDM n.
2150026

1.10 / Technical data
Kit for the qualitative determination of the new coronavirus antigen, using nasopharyngeal and / or throat swabs. Result in 15 minutes. High precision, specificity and sensitivity.

1.11 / Inteded use
Rapid self-diagnosis for new coronavirus.

1.12 / Storage and instruction for use
Store at a temperature between 4° and 30°C
Store in a dry environment
Do not expose directly to sunlight



2.01 / Primary packaging

Quantity	1 pcs
Size	20x11,5x10 mm
Weight-material	30 gr. – PVC pack

2.02 / Secondary packaging and palletization

Quantity	400 pcs
Size	63x35x28 cm
Weight- material	13,5kg –Corrugated card.
Pallet	n.d.