CORONA VIRUS (COVID-19) ANTIGEN RAPID TEST (COLLOIDAL GOLD)

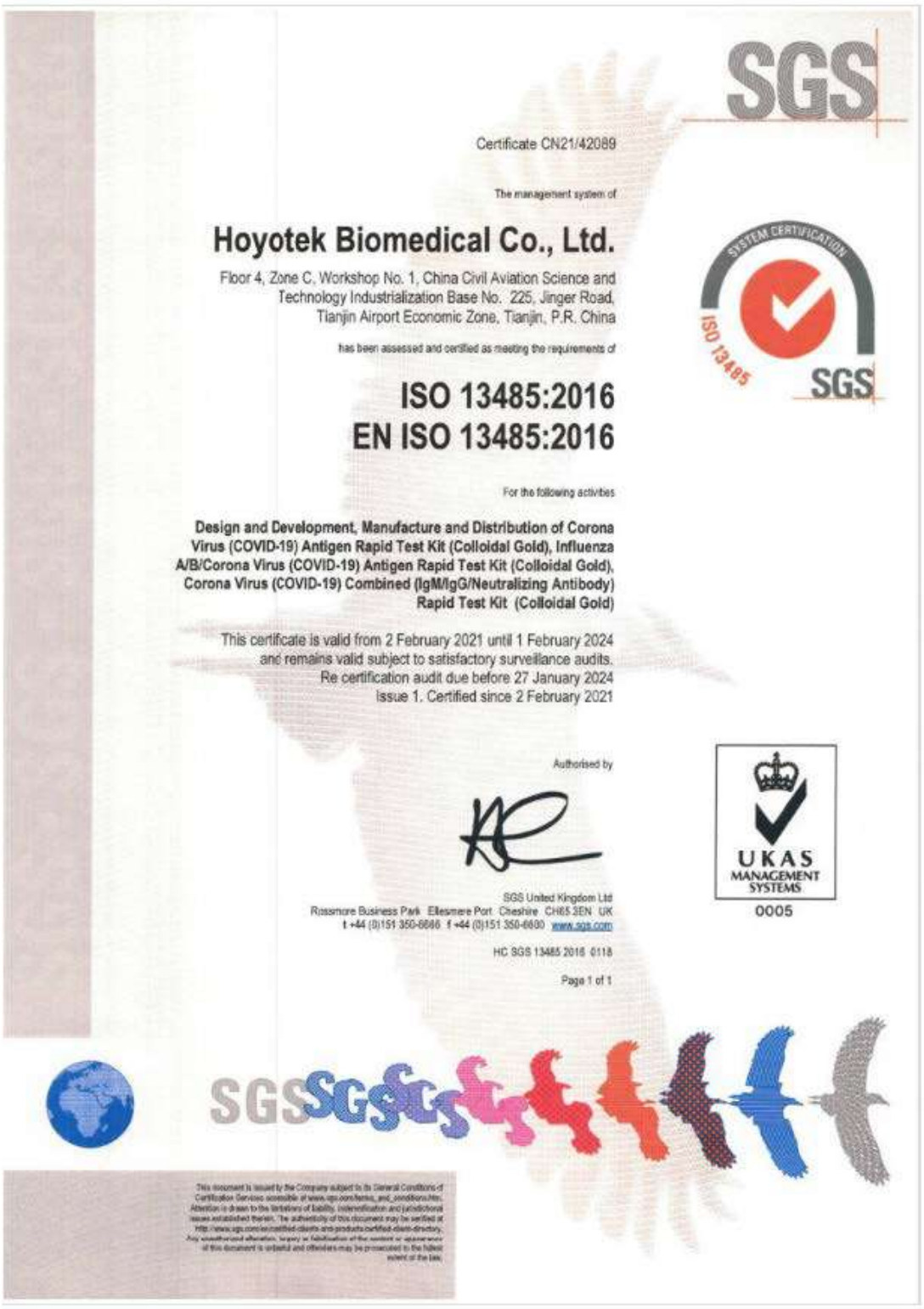
Nome Prodotto	HYT-G01
Colore	Neutro
Confezionamento	Confezione singola 30 pezzi
Dimensione	Standard
Tipo di prodotto	Test Rapido

Produttore: Hototek Biomedikal Co., Ltd

Il kit per il test rapido dell'antigene COVID-19 (tampone) viene utilizzato per il rilevamento qualitativo degli antigeni proteici nucleocapside da campioni di tamponi nasali o nasofaringei del corpo umano. Viene utilizzato solo come supplemento al test dell'acido nucleico del nuovo coronavirus o in combinazione con il test dell'acido nucleico nei casi sospetti. Non può essere utilizzato come base per la diagnosi e l'esclusione della polmonite causata da una nuova infezione da coronavirus. I risultati di questo kit sono solo di riferimento clinico. Se il risultato del test è positivo, è necessaria un'ulteriore conferma. Se il risultato del test è negativo, non si può escludere la possibilità di infezione. Un'analisi completa delle caondizioni del paziente deve essere eseguita in combinazione con i sintomi clinici e altri test di laboratorio.

Il test rapido dell'antigene COVID-19 è destinato a operatori sanitari o operatori addestrati che hanno familiarità con il test rapido dell'antigene.

CERTIFICATI



SGS

Certificate CN21/42089

The management system of

Hoyotek Biomedical Co., Ltd.

Floor 4, Zone C, Workshop No. 1, China Civil Aviation Science and Technology Industrialization Base No. 225, Jinger Road, Tianjin Airport Economic Zone, Tianjin, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design and Development, Manufacture and Distribution of Corona Virus (COVID-19) Antigen Rapid Test Kit (Colloidal Gold), Influenza A/B/Corona Virus (COVID-19) Antigen Rapid Test Kit (Colloidal Gold), Corona Virus (COVID-19) Combined (IgM/IgG/Neutralizing Antibody) Rapid Test Kit (Colloidal Gold)

This certificate is valid from 2 February 2021 until 1 February 2024 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 January 2024
Issue 1. Certified since 2 February 2021

Authorised by

SYSTEM CERTIFICATION ISO 13485 SGS

UKAS MANAGEMENT SYSTEMS 0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

Page 1 of 1

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CERTIFICATI

Declaration of conformity

Hoyotek

Manufacturer: Hoyotek Biomedical Co., Ltd.
Floor 4, Zone C, Workshop No.1, China civil Aviation science and technology industrialization base No. 225, Jinger Road, Tianjin Airport Economic Zone.

European Representative: QAdvis EAR AB
Ideon Science Park
Scheelevägen 17 SE-223 70 Lund, Sweden

Product Name: Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)
Influenza A/B/Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)
Corona Virus (COVID-19) Combined (IgM/IgG/Neutralizing antibody) Rapid Test (Colloidal Gold)

Product Model: HYT-G01, HYT-G02, HYT-G03

Classification: Other IVD Devices

Conformity assessment Route: IVDD 98/79/EC Annex III

We, Hoyotek Biomedical Co., Ltd hereby declare that the devices mentioned above comply with applicable parts of the Swedish In-Vitro Diagnostic Medical Device Act SFS 1993:584, and the Swedish national legislation LVFS 2001:7, transposing the European In-Vitro Diagnostic Medical Devices Directive, IVDD 98/79/EC.

Verification to: Standard ISO13485:2016, EN ISO14971:2012, EN ISO15223-1:2016, EN ISO18113-1:2011, EN ISO 18113-2:2011, EN ISO18113-3:2011
Related to Directive(s):
98/79/EC (in Vitro Diagnostic Medical Devices)

Approved by:

General Manager : Wu Bo

Tianjin Wu Bo 2020.11.17

Name | Signature
Function | Place and Date of issue

CERTIFICATI

QAdvis EAR European Authorized Representative

Certificate of CE registration

QAD 1056

Manufacturer name and address: Hoyotek Biomedical Co. Ltd.
Floor 4, Zone C, Workshop No.1, China civil Aviation science and technology industrialization base No. 225, Jinger Road, Tianjin Airport Economic Zone, China

Product name:	Model:
Corona Virus (COVID-19) Antigen Rapid Test (colloidal gold)	HYT-G01
Influenza A/B/Corona Virus (COVID-19) Antigen Rapid Test (colloidal gold)	HYT-G02
Corona Virus (COVID-19) Combined (IgM/IgG/Neutralizing antibody) Rapid Test (colloidal gold)	HYT-G03

QAdvis EAR as a European Authorized Representative designated by the manufacturer certifies that the products listed above have been notified and filed at the Competent Authority, Swedish Medical Products Agency, as CE-marked In Vitro Diagnostic Medical Devices in accordance with the In Vitro Diagnostic Medical Devices Directive 98/79/EC, article 10.3.

The manufacturer has provided QAdvis EAR with Declaration of Conformity declaring conformance with the requirements in In Vitro Diagnostic Medical Devices Directive 98/79/EC.

Registration data at Swedish Medical Products Agency:

Reference number: 1607413694862
Initial notification to Swedish Medical Products Agency for the products listed above on 2020-12-08.

Date: 2020-12-08

Bing Wu
EAR manager

QAdvis is a member of

EC REP

QAdvis EAR AB
Address: Ideon Science Park, Scheelevägen 17, SE-223 70 Lund, Sweden
Tel office: +46 8 621 01 05, Email: ear@qadvis.com, Web: www.qadvis.com

CERTIFICATI

Hoyotek

Hoyotek Biomedical Co., Ltd.
Floor 4, Zone C, Workshop No.1, China civil Aviation science and technology industrialization base No. 225, Jinger Road, Tianjin Airport Economic Zone.

Letter of Declaration

To whom it may concern,

We, Hoyotek Biomedical Co., Ltd., located at No. 225 Jinger Road, Tianjin Airport Economic Zone, China, hereby declare that our Product of Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold) remain effective for the detection of SARS-CoV-2 antigen and are theoretically able to detect the Omicron variant (B.1.1.529) of the SARS-CoV-2 virus found in South Africa.

Experiments were conducted on product of the Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold) using the recombinant SARS-CoV-2 Omicron Variant Protein for reevaluation of the sensitivity of the product. The experiment result proves that the product is able to detect the Omicron and meet the required standards .

Yours sincerely,

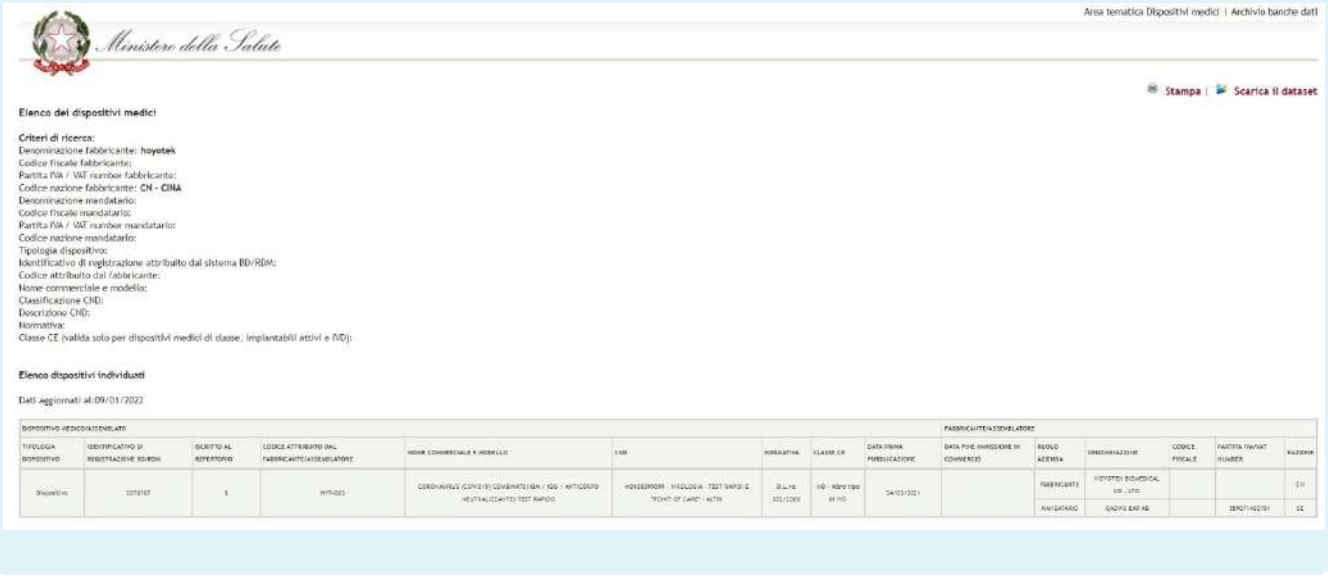
天津鸿宇泰生物科技有限公司
Hoyotek Biomedical Co., Ltd.
Hoyotek Biomedical Co., Ltd.

Date: December 14, 2021

CERTIFICATI

Manufacturer	RAT commercial name	Device ID # [25]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Hoyotek Biomedical Co.,Ltd.	Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)	1929	*Retrospective in vitro study* DE: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 90% at Ct ≤ 25; Manufacturer specificity: 99%	NP swab - Sensitivity: 96%, Specificity: 99% OP swab - Sensitivity: 93%, Specificity: 97.5%	DE[2]		DE[2]	*Unknown*	20 October 2021
Hubei Jinjian Biology Co., Ltd	SARS-CoV-2 Antigen Test Kit	1759	*Retrospective in vitro study* DE: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.3%	Sensitivity: 98.02% Nasal Swab	DE[2]		DE[2]	*Unknown*	23 July 2021
Humasis	Humasis COVID-19 Ag Test	1263	*Retrospective in vitro study* DE: Positive evaluation by Paul-Ehrlich-Institut (NP swab): Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%	95.3% sensitivity 100% specificity Nasal swab	AT, BE, BG, DE[2], FR, HR, SE, SI		DE[2] UK	*Unknown*	10 May 2021
Innova Medical Group.Inc	Innova SARS-CoV-2 Antigen Rapid Qualitative Test	1801	*Retrospective in vitro study* DE: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%	Sensitivity 94.0% : CI 95% (86.7%-98.0%) – calculated for viral loads x10^6 copies RNA /mL Specificity: 99.6% - CI:95%(99.4%-99.8%)	DE[2]		DE[2]	Nucleo-capsid protein	20 October 2021
Innovation Biotech(Beijing) Co.Ltd	Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Nasal swab)	2278	*Retrospective in vitro study* DE: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%	Sensitivity: 95.6% Specificity: 100%	DE[2]		DE[2]	Nucleo-protein	20 October 2021
InTec PRODUCTS, INC.	Rapid SARS-CoV-2 Antigen Test (nasopharyngeal specimen)	2419	*Retrospective in vitro study* DE: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	Sensitivity 90.2% (95% CI: 83.1% to 95.0%); Specificity 100.0% (95% CI: 96.5% - 100.00%)	DE[2]		DE[2]	Nucleo-capsid protein	20 October 2021
Jiangsu Bioperfectus Technologies Co., Ltd.	Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit	2107	*Retrospective in vitro study* DE: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.15%	97.06 % sensitivity 99.15 % specificity Nasal/NP/ OP swab	DE[2]		DE[2] UK	*Unknown*	14 July 2021
Jiangsu Diagnostics Biotechnology Co., Ltd	COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)	1920	*Retrospective in vitro study* DE: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	97.58 % sensitivity 100 % specificity Nasal/NP/ OP swab	DE[2]		DE[2]	*Unknown*	14 July 2021

REGISTRAZIONE MINISTERO DELLA SALUTE



Area tematica Dispositivi medici | Archivio banche dati

Ministero della Salute

Stampa | Scarica il dataset

Elenco dei dispositivi medici

Criteri di ricerca:
Denominazione fabbricante: **hoyotek**
Codice Fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante: **CN - CINA**
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM:
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Normativa:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:09/01/2022

DISPOSITIVO MEDICO/ASSEMBLATO									FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD-RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	NORMATIVA	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	1074787	S	HYT-001	CORONAVIRUS (COVID-19) COMBINATO/AN / IGG / ANTICORPO NEUTRALIZZANTE) TEST RAPIDO	H0102090599 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	D. L.vo 332/2000	IVD - Altro tipo di IVD	04/03/2021		FABBRICANTE	HOYOTEK BIOMEDICAL CO., LTD.			CN
										MANDATARIO	QIAOYE EAR AB		SE5071402701	SE

MISURE IMBALLO

1) Misura cartone imballo 60*40*40*

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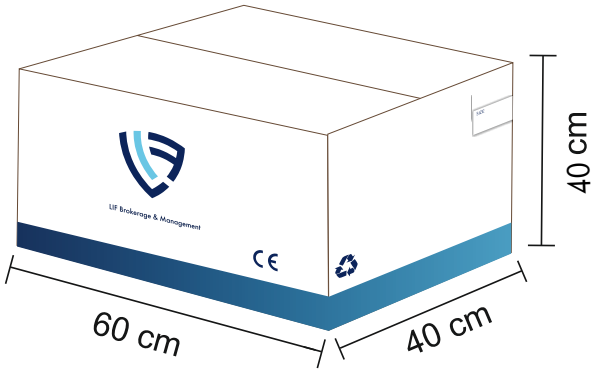

CONSERVAZIONE / USO FINALE

Si consiglia di conservarlo in cartone o scatola di cartone, al riparo dalla luce solare, tra 15-25 °. Se conservato in condizioni adeguate, si consiglia di utilizzarlo entro 3 anni dalla data di produzione.

AVERTENZE

Questo è solo una guida indicativa. Non deve essere utilizzata come unica metodologia di selezione dell'indumento di protezione. Prima di utilizzare qualunque indumento di protezione l'utilizzatore deve averletto e capito tutte le istruzioni d'uso del prodotto. E necessario asservare la legislazione vigente in ogni singolo paese.

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