



AT UYGUNLUK BEYANI EU DECLARATION OF CONFORMITY

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|--|---|
| Üretici / Manufacturer | Unioninvest Ltd. Sti. Skyport Residence, No: 1/64, Beylikduzu, Istanbul Turkey |
| Ürün / Product | Covid-19 Antigen Rapid Test Kit (Colloidal Gold) |
| Marka / Brand | Unibioscience |
| Model | Cassette |
| Sınıfı / Class | Vücut Dışında Kullanılan Diğer Tıbbî Cihazlar / Other IVD Devices |
| Uygunluk Değerlendirme Prosedürü / Conformity assesment procedure | Directive 98/79/EC Annex III |
| Uygulanabilir Standartlar / Applicable Standards | |
| EN ISO 13485:2016 | Medical devices - Quality management systems – Requirements for regulatory purposes |
| EN ISO 9001:2015 | Quality management Systems - Requirements |

Yukarıda açıklanan ürünlerin 98/79 / EC direktifine uygun olduğunu tamamen kendi sorumluluğumuzda beyan ederiz. Ürünler CE işaretlidir.

We declare under sole responsibility that the products described above as delivered complies with directive 98/79/EC. The products are CE marked.

Istanbul, 24.08.2020


Orhan Avur
General Manager



**UKS INTERNATIONAL
QUALITY SYSTEMS &
CERTIFICATION LTD.**

This is to certify

**Unioninvest Gida Turizm Sanayi Ve
Dis. Tic. Ltd. Sti.**

**Yakuplu Mh. Hurriyet Bulv. Skyport No:1
Ic Kapi No: 64 Beylikduzu / ISTANBUL
TURKEY**

*Has been assessed by UKS and found to be in compliance
with the following standard*

ISO 9001:2015

The Medical Devices Management System is applicable to

**Development, Production And Sales Of Medical Diagnostic Products Used Out
Of Body, Laboratory Material, Kit And Devices**

Category / Sub Category : ---
Certificate No :MSQ-0213
Certificate First Issue Date :05th September 2020
Decision Date :05th September 2020
Certificate Issue Date :05th September 2020
Expiration Date :04th September 2021

This certificate is valid for 3 years after first certification or re-certification decision date, in case of,
firms to comply with UKS's Certification Rules and be successful in the surveillance audit made at least once a year.
FR.73/Issue Date:01.05.2013/Rev. Date:14.03.2019/Rev. No:04



General Manager





This is to certify

**Unioninvest Gida Turizm Sanayi Ve
Dis. Tic. Ltd. Sti.**

**Yakuplu Mh. Hurriyet Bulv. Skyport No:1
Ic Kapi No: 64 Beylikduzu / ISTANBUL
TURKEY**

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with the following standard*

ISO 13485:2016

The Medical Devices Management System is applicable to;

**Development, Production And Sales Of Medical Diagnostic Products Used Out
Of Body, Laboratory Material, Kit And Devices**

Category / Sub Category : ---
Certificate No :MDQ-0102
Certificate First Issue Date :05th September 2020
Decision Date :05th September 2020
Certificate Issue Date :05th September 2020
Expiration Date :04th September 2021

This certificate is valid for 3 years after first certification or re-certification decision date, in case of,
firms to comply with UKS's Certification Rules and be successful in the surveillance audit made at least once a year.
FR.73/Issue Date:01.05.2013/Rev. Date:14.03.2019/Rev. No:04



General Manager



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**Yakuplu Mh. Hurriyet Bulv. Skyport No:1
Ic Kapi No: 64 Beylikduzu / ISTANBUL
TURKEY**

*Has been assessed by UKS and found to be in compliance
with the following standard*

GMP

Good Manufacturing Practice

The Good Manufacturing Practice System is applicable to;

**Development, Production And Sales Of Medical Diagnostic Products Used Out
Of Body, Laboratory Material, Kit And Devices**

Category / Sub Category : ---
Certificate No :MSU-0012
Certificate First Issue Date :05th September 2020
Decision Date :05th September 2020
Certificate Issue Date :05th September 2020
Expiration Date :04th September 2021

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surveillance audit made at least once a year.
FR.73/Issue Date:01.05.2013/Rev. Date:14.03.2019/Rev. No:04



Genel Müdür

