



Provide evidence that another EU member state has already granted an exemption for use of the rapid antigen test as a self-test.

So far, our company has applied for self-test in Austria and Germany of European Union. The specific information is as follows:

1. Official website of Austria

We have been included in the name list published on the website below:

<https://www.basg.gv.at/fuer-unternehmen/medizinprodukte/covid-19>.

Here is the screenshot from the documents published.

Shenzhen Dymind Biotchnology Co., Ltd.	10th Floor, Building B, Hightech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107, P. R. China	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	Shenzhen Dymind Biotchnology Co., Ltd. 10th Floor, Building B, Hightech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107, P. R. China	SUNGO Europe B.V. Olympisch Stadion 24, 1076 DE Amsterdam, Netherlands
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2. Official website of Germany

We have submitted the application (Test-ID: AT260/21) to Bfarm for the professional test and which has been published on the website below:

https://www.bfarm.de/EN/MedicalDevices/AntigenTests/_node.html

Here is the screenshot from the documents published.

Test-ID	Handelsname des Hersteller (Empf. Handelsnamen)	Erstzulassung PEI	Name (L)	Stadt	Land	Name	Stadt	Land	Deutschland Hersteller	Testort	% Sensitivität	% Spezifität		
AT260/21	SUNGO-COVID-2-Antigen-Testkit (Colloidal Gold)	Nein	Shenzhen Dymind Biotchnology Co., Ltd.	Shenzhen	CN	SUNGO Europe B.V.	Amsterdam	NL	POC ohne Verpackung		98,36	92,11 - 98,27	97,56	93,64 - 99,33
AT260/21	SUNGO-COVID-2-Antigen-Testkit (Colloidal Gold)	Nein	Shenzhen Dymind Biotchnology Co., Ltd.	Shenzhen	CN	SUNGO Europe B.V.	Amsterdam	NL	POC ohne Verpackung		98,36	91,40 - 99,30	98,27	94,20 - 99,89

3. Special approval proceeding in Germany

At the same time, we are in the process of special approval application. And the application Number is 5640-S-197/21.