Checklist of the Application Documents

No.	Content	Explain
1	The applicant must be able to demonstrate that the rapid antigen test in question already bears a CE-mark for professional use.	The CE registration evidence and Declaration of conformity was provided.
2	The applicant must be able to demonstrate that they have already started a conformity assessment procedure with a notified body to obtain a CE-mark for the use of the rapid antigen test as a self-test.	We provided 2 rejection letters from NB 1023 and NB 0373.
3	The suitability of the rapid antigen test as a self-test has been demonstrated for a specifically defined target group.	The IFU defined this.
4	The rapid antigen test satisfies the requirements for devices for self-testing as set out in the Decree on in vitro diagnostic medical devices (IVDs) and existing standards for self-tests (with the exception of the design-examination certificate for self-tests, issued by a notified body).	The checklist of the essential requirements was provided and the whole technical files were provided.
5	All documentation must be supplied in English or Dutch.	All in English except the IFU, which is in Dutch.
6	The application must include the contact details of an individual to whom questions about the application and the documentation can be directed.	Cover Letter
7	The application must state if the rapid antigen test is included in the most recent version of the Health Security Committee's 'A common list of COVID-19 rapid antigen tests',1 published on 17 February 2021.	Cover Letter
8	The application must state whether another EU member state has already granted an exemption for use of the rapid antigen test as a self-test.	Part 17 of the application documents
9	The submitted file must have a clear structure and a table of contents and must be easy to search.	Table of content was provided
10	The applicant must have a post-market surveillance system in place for recording and assessing experiences with using the rapid antigen test as a self-test, based on which appropriate measures can be taken if necessary.	The applicant has a post market surveillance system in place

11	Any reports of incidents and safety issues related to self-administering the test in question must be reported immediately to the Health and Youth Care Inspectorate (IGJ).	This was included in the post market surveillance system.
12	The applicant must comply with the regular statutory vigilance procedures relating to general safety and performance requirements.	The applicant has vigilance procedures in place.
13	If the applicant obtains a CE-mark for use of the rapid antigen test as a self-test, they must inform IGJ and the Pharmaceuticals and Medical Technology Department (GMT) of the Ministry of Health, Welfare and Sport via 5.1.2e minvws.nl.	So far, the applicant has not got the CE for the self-test kit.
14	Exemptions granted are published on rijksoverheid.nl.	OK
15	While processing the application, the Ministry of Health, Welfare and Sport may request supplementary documentation or make changes if necessary. Applicants will be informed in good time and will have an opportunity to amend their application where necessary.	OK

Cover Letter

SARS-CoV-2 Antigen Test Kit (Colloidal Gold)
For self-test only

Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd.
Address:10th Floor, Building B, High-tech park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen, 518107, P.R.China

The rapid antigen test is not included in the most recent version of the Health Security Committee's 'A common list of COVID-19 rapid antigen tests', published on 17 February 2021.

Contact: 5.1.2e
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List of the File

No.	Document title
1	CE for Professional Use
2	Rejection Letter from Notify Body of SARS-Cov-2 Antigen Self-test-2
3	Product Name
4	Principle of the Test
5	Test Kit description
6	Example of Packaging Diagram
7	Clinical Evaluation
8	Extrapolation of the Validation Data to Dutch Situation
9	Performance Characteristics and Stability Study
10	Usability Report
11	Instruction for Use
12	Test Kit Component
13	DOC of the Test Kit
14	DOC of the Accessories
15	Essential Requirements Check-list for Non-expert Using
16	Risk Management Report
17	Special Approval in Another EU Country
18	Instructions from the Dutch Government