帝迈生物 DYMIND BIOTECH	Shenzhen Dymind Biotechnology Co., Ltd	Document No.: DMR003-CE-003A-03
		Version: V1.0
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Project Name:

SARS-CoV-2 Antigen Test Kit (Colloidal Gold)

Document Name:

Usability Engineering File

According to EN 62366-1:2015

Drafted by: 5.1.2e	Checked by: 5.1.2e	Approved by: 5.1.2e
Date: 2021.04.15	Date: 2021.04.15	Date: 2021.04.15

Summarized review comments:(another page could be attached if not enough)

Revision records

Version	Summarized Revisions	Written by	Revised Date
V1.0	Initialization Version	5.1.2e	2021.04.15

Table contents

1. Objective

This self-testing usability and label comprehension of the SARS-CoV-2 Antigen Test Kit (Colloidal Gold) is to ensure that the users can correctly operate the product. The evaluated product SARS-CoV-2 Antigen Test Kit (Colloidal Gold), which is an in vitro diagnostic device. Product specification and package information are listed in below table.

Table 1. Product specification and package information

Specification / Component	1 test/ kit	1 test/ kit	1 test/ kit	6 tests/ kit	20 tests/ kit	20 tests/ kit	20 tests/ kit
Test Cassette	1	1	1	6	20	20	20
sample tube with extraction reagent	1×0.5 mL	1×0.5 mL	/	/	20×0.5 mL	20×0.5 mL	/
Nasal Swab	1	/	/	/	20	/	/
Instruction for use	1	1	1	1	1	1	1

2. Product description

2.1 General information

The novel coronaviruses belong to the βgenus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

The median incubation time is estimated to be 5.1 days with symptoms expected to be present within 12 days of infection. The symptoms of COVID-19 are similar to other viral respiratory diseases and include fever, cough and shortness of breath.

2.2 Principle of the test

The SARS-CoV-2 Antigen Test Kit is a rapid lateral flow immuno-chromatographic sandwich assay to directly detect nucleocapsid protein of SARS-CoV-2 in nasal swab specimens and diagnosis of SARS-CoV-2 infection.

The patient sample is placed in the Sample Tube, during which time the virus particles in the sample are disrupted, exposing internal viral nucleoproteins. After disruption, the sample is added into the Test Cassette sample well. And the sample migrates through a test strip, if the SARS-CoV-2 virus antigen is present, a red color line will be showed on the T line. If SARS-CoV-2 viral antigen is absent, there is not a red line will be showed on the T line, however, a red line will be always showed on the C line indicating that the reaction system is properly happened.

2.3 Product specifications and packages

See Table 1.

3. Device USE SPECIFICATION

3.1 Purpose

3.1.1 Intended use

The SARS-CoV-2 Antigen Test Kit is a gold immuno-chromatographic assay (GICA) that is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal (NS) swab specimens. This product is for self-testing only.

3.1.2 Precautions

1) For in vitro diagnostic use only.
2) Please read this manual carefully prior to using this test kit. And follow the testing procedures strictly described in the manual, otherwise it will lead to incorrect results.
3) Do not use expired reagents.
4) Do not re-use the test kit.
5) All samples, used reagents, test cards, and other materials used during testing are considered to be infectious, and personal protection should be done during the experiment.
6) Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples. Wear suitable protective clothing and eye/face protection when handling the contents of this kit.
7) Sample handling and waste disposal must comply with relevant regulations. Wash hands thoroughly after handling.
8) Avoid using visually bloody or overly viscous samples for testing.
9) Do not use components from different batch lots.
10) The sample tube contains a salt solution. If the solution contacts the skin or eye, flush with copious amounts of water.
11) Rinse your mouth with water 30 minutes before sampling, and do not eat, smoke, drink alcohol or drinks after rinsing.

3.1.3 Storage and stability

1) The test device is sensitive to humidity as well as to heat.
2) Store kit components at 2-30°C, out of direct sunlight. The validity period is 12 months. Within the period of validity the kit components are stable.
3) After unsealing the aluminum foil bag, the test cassette should be used as soon as possible within Two hours.
4) Do not freeze.

3.1.4 Limitations

1) This test is for in vitro diagnostic use only.
2) A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
3) Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
4) Test results must be evaluated in conjunction with other clinical data available to the physician.
5) This test cannot distinguish between asymptomatic carriers and infected persons of the

SARS-CoV-2.

6) A false negative result may be obtained if the concentration of the viral antigen in the nasal swab is below the sensitivity.
7) Negative results should be treated as presumptive and confirmed with an approved molecular assay.
8) Clinical performance was evaluated with frozen samples, and performance may be different with fresh samples.

3.2 Patient Population

a) Age: not relevant
b) Gender: not relevant
c) Weight: not relevant
d) Health: not relevant
e) Nationality: multiple
f) Patient state:
   - Patient is the Operator: able to read instruction of use; People without visual impairment;
   - Patient is not the Operator: unable to read instruction of use; with visual impairment;

3.3 Part of the body or the type of tissue applied to or interacted with

The nasal (NS) swab will be contacted with people's nasal.

3.4 Intended User (User profile)

Laypersons.

a) Education: not relevant
b) Knowledge:
   - Able to read and understand instruction of use
   - No maximum
c) Language understanding:
   - Understand the language provided in the IFU
d) Experience: no special experience needed

3.5 Application

a) Environment:
   - Home use, not intended for professional use
b) Conditions of visibility:
   - Viewing distance: 20cm to 40cm
c) Physical:
   - Room temperature
   - Relative humidity range: not relevant
d) Frequency of use:
   - Single use.
e) Mobility:
   - Portable. After use, the device should be discarded.
f) Use place:
   - Home setting.

4. Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS

4.1 Primary operating function

For nasal sample:

a) Use nasal swabs and throat swabs to collect sample through the nostrils or mouth

b) Place the swab into the sample tube that has been pre-filled with 0.5 mL sample buffer, rotate the swab for about 10 seconds.

c) Press the sample tube to release the antigen in the swab and take out the swab.

d) Install the dropper cap onto the sample tube.

e) Add two drops of the extraction sample into the sample well

f) Read the result within 15 minutes.

g) Interpret test result.

4.2 User interface related to the device

No.	User interface		Related to SAFETY or not?	Potential USE ERRORs
1.	Accompanying documentation	Label	Yes	Misreading, wrong reading,
2.		IFU	Yes	Misreading, wrong reading, incorrect operation methods/wrong operation
3.	Test cassette		Yes	Misreading test line;
4.	Dropper		Yes	Mis-Dropping
5.	Sample tube with extraction reagent		Yes	Incorrectly prepare sample
6.	Nasal Swab		Yes	Incorrectly collect samples

4.3 Possible Use errors

Sources: Literature, Complaint file, Adverse Event of similar devices, Risk Analysis, etc.

a) During normal use:
- Breaking of the device;
- Solution leakage;
- Head of Swab fall off

b) Use errors:
- Reuse the device which had been used;
- Cross use the device;
- Use the device with damaged package;
- Process the device not according to the Step-by-Step instructions;
- Improper operation methods;
- Wrong sampling of Swab;
- Wrong storage environment;
- Solution contacts the skin or eye;
- Wrong number of drops;

c) Environment:
- Used in the outdoor;
- Incorrect storage environment;

d) Patient
- Operated the device by patient with unable read the IFU or with visual impairment

e) Reading:

- Misread the product label & IFU;
- Misread the test line;

f) Hygiene:
- Cross-contamination;
- Infection;

4.4 Hazardous situations and harms

No.	Hazardous situations	Harms
1.	Patients exposed to polluted products	Infection
2.	Breaking of the swab	Solution leakage, injury the patient
3.	Patients are inserted with reused products	infection
4.	Use confuse of models	failure of sampling, delay the diagnosis
5.	Improper invert times	invalid lysis
6.	Use the expired Tube reagent Solution	sampling failure; delay the diagnosis
7.	Use the expired Swab	Maybe result in contamination or infection
8.	Incorrect storage (low temperature)	Result in frozen, delay the sampling, diagnosis
9.	Incorrect disposal the used device	Contaminate the environment
10.	Reuse the Swab	Contamination or infection
11.	Reuse the tube	delay the sampling, diagnosis
12.	Wrong symbol in the label	Result in use error; delay the sampling
13.	Wrong operating steps	Result in use error; delay the sampling
14.	Wrong number of drops	Result in incorrect diagnosis
15.	Incorrect dropping	Incorrect test results
16.	Fail to close the cap	Leakage, delay the diagnosis

4.5 User interface specification

a) Select materials for the swabs, tubes according to standards;
b) Correct labels and information of the devices;
c) Provide "Instruction for use" to the Users;
d) Clear and correct symbol on the label;
e) Provide the detailed Step-by-Step instructions for operation;
f) Sampling diagram of the devices should be clearly shown in IFU;
g) Demonstrate the important information about application of the devices in IFU such as "Warnings, Precautions" and so on;
h) No leakage design;
i) Readable/legible mark;

4.6 Preliminary User interface evaluation

Note: This review could be conducted utilizing a combination of cognitive walkthroughs, mock-up testing and early prototype testing.

For nasal sample:

a) Use nasal swabs and throat swabs to collect sample through the nostrils or mouth
   - Follow the procedures according to related IFU;
   - Easy to sample;
   - The head of swab will not drop off;

   Conclusion: No problem.

b) Place the swab into the sample tube that has been pre-filled with 0.5 mL sample buffer, rotate the swab for about 10 seconds.
   - Follow the procedures according to related IFU;
   - The detailed operation steps described in the IFU;
   - Easy to insert the swab into the tube;

   Conclusion: No problem.

c) Press the sample tube to release the antigen in the swab and take out the swab.
   - Follow the procedures according to related IFU;
   - The detailed operation steps described in the IFU;
   - Easy to operation;

   Conclusion: No problem.

d) Install the dropper cap onto the sample tube.
   - Follow the procedures according to related IFU;
   - The detailed operation steps described in the IFU;
   - Easy to operation;

   Conclusion: No problem.

e) Add two drops of the extraction sample into the sample well
   - Follow the procedures according to related IFU;
   - The detailed operation steps described in the IFU;
   - Easy to operate the dropper;

   Conclusion: No problem.

f) Read the result within 15 minutes.
   - Follow the procedures according to related IFU;
   - The detailed operation steps described in the IFU;
   - Easy to follow.

   Conclusion: No problem.

g) Interpret test result.
   - Follow the procedures according to related IFU;
   - The detailed operation steps described in the IFU;
   - Easy to identify the test line;
   - The mark is showed very clearly;

   Conclusion: No problem.

5. Usability specification

5.1 General

a) **Device**

SARS-CoV-2 Antigen Test Kit (Colloidal Gold).

b) **Basis:**
   - Intended use, see 3.1.1
   - Possible use error, see 4.2, 4. 3

- Hazardous situation or harms related to use, see 4.4
- Context of use
  - Background noise from the outdoor
  - At home, room temperature
- Preliminary use scenarios
  - Open the bag, take out the swab
  - Open the aluminum foil bag, put the test cassette on the bench
  - Place the swab into the nostril, gently rotate the swab several times then remove it from the nostril
  - Place the swab into the sample tube, rotate the swab for about 10s
  - Press the sample tube to release the antigen in the swab and take out the swab.
  - Install the dropper cap onto the sample tube, add two drops of the extraction sample into the sample well and start the timer
  - Read the results within 15minutes.

5.2 Use scenarios

The SARS-CoV-2 Antigen Test Kit (Colloidal Gold) is an in vitro diagnostic device. The device is used in the home setting, not intended for professional use.

The user must can read the instructions for use, and understand how to operate it, user with visual impairment need to use it with the help of others.

Worst case use scenarios to provide a basis for validation with patient = user:

5.2.1 Scenarios 1:

At home, room temperature

Procedure: for nasal sample:

a) Use nasal swabs to collect sample through the nostrils
b) Place the swab into the sample tube that has been pre-filled with 0.5 mL sample buffer, rotate the swab for about 10 seconds.
c) Press the sample tube to release the antigen in the swab and take out the swab.
d) Install the dropper cap onto the sample tube.
e) Add two drops of the extraction sample into the sample well
f) Read the result within 15 minutes.
g) Interpret test result.

5.3 User interface requirements for the primary operating functions

The labels and markings of the devices such as Type, Specification are provided to the users.

a) Swabs
   - Easy to hold
   - Comfortable head of swab
   - Appropriate length for sampling swab

b) Sample tube
   - Easy to hold
   - Easy to cover the cap, and tighten it
   - Extraction sample well drop out of tube

c) Dropper
   - Easy to suction the extraction sample

d) Test cassette
   - Clear mark to identify

e) IFU
- Easy to understand
- Appropriate font size
- Clear and comprehensive schematic diagram

f) Label
- Correct icon
- Adequate label information

5.4 User interface requirements for those Use scenarios that are frequent or related to safety

a) The whole procedure shall be easy to do after reading the IFU. Product Name, Performance structure, Indications, Precautions, Potential adverse reaction, Contraindications, Operation methods, Storage and transportation, Explanation of symbols

b) Text: The expected user's language font size is 9-20pt.

c) Symbols proven to be intuitive for intended USERS.

d) Readable/legible mark in the label.

e) Clear Sampling diagram showed in the Procedure card.

5.5 Requirements for determining whether primary operating functions are easily recognizable by User

a) Labels and markings of the devices:
- The correct type and specification of the device;

b) IFU of the devices:
- Principles, Precautions, Operations, Storage, Samplings, etc.

6 Usability Engineering Conclusion

This product follows EN 62366 above and has satisfied the acceptance criteria in the usability validation protocol, therefore, the usability related residue risks of this product are acceptable according to EN ISO 14971. The user interface design meets the requirements of operating specifications, meets the intended use and application.

7 Reference

1) EN 62366:2008 Medical devices -Application of usability engineering to medical devices
2) EN 62366-1:2015 Medical devices –Part 1: Application of usability engineering to medical devices
3) IEC TR 62366-2:2016 Medical devices – Part 2: Guidance on the application of usability engineering to medical devices
4) EN ISO 14971:2012 Medical devices — Application of risk management to medical devices
5) EN ISO 14971:2019 Medical devices — Application of risk management to medical devices
6) DMR003-CE-001A V1.0 Instructions for Use

帝迈生物 DYMIND BIOTECH

帝迈生物 DYMIND BIOTECH	**Shenzhen Dymind Biotechnology Co., Ltd**	Document No.: DMR003-CE-003A-04
		Version: V1.0
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Project Name:

SARS-CoV-2 Antigen Test Kit (Colloidal Gold)

Document Name:

Self-testing Usability checklist

(according to IEC 62366)

Drafted by: 5.1.2e	Checked by 5.1.2e	Approved by: 5.1.2e
Date: 2021.04.17	Date: 2021.04.17	Date: 2021.04.17

Summarized review comments:(another page could be attached if not enough)

Revision records

Version	Summarized Revidions	Revisor	Revised Date
V1.0	Initialization Version	5.1.2e	2021.04.17

Self-testing Usability checklist

(according to IEC 62366)

帝迈生物 DYMIND BIOTECH

IEC 62366 Medical devices Application of usability engineering to medical devices	
Report Reference No. ..... :	Usability report
Date of issue…….. ……:	2021.03.12
Total number of pages	21
CB Testing Laboratory ..... :	N/A
Address ..... :	N/A
Applicant's name ..... :	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
Test specification:	
Standard ..... :	IEC 62366-1:2015
Test procedure ..... :	CB
Non-standard test method…….. :	N/A

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

Test item description ..... :	**SARS-CoV-2 Antigen Test Kit (Colloidal Gold)**
Trade Mark ..... :	
Manufacturer ..... :	Shenzhen Dymind Biotechnology Co., Ltd.
Model/Type reference..... :	10th Floor, Building B, High-tech park,Guangqiao Road, Tianliao Community,Yutang Street, Guangming District, Shenzhen, 518107, P.R.China
Ratings ..... :	

帝迈生物 DYMIND BIOTECH

Usability checklist

Testing procedure and testing location:	
☐ **CB Testing Laboratory:** Testing location/ address.....: ☐ **Associated CB Test Laboratory:** Testing location/ address.....: Tested by (name + signature).....: Approved by (+ signature).....:	N/A
☐ Testing procedure: TMP Tested by (name + signature).....: Approved by (+ signature).....: Testing location/ address.....:	N/A
☐ Testing procedure: WMT Tested by (name + signature).....: Witnessed by (+ signature) .....: Approved by (+ signature).....: Testing location/ address.....:	N/A
☐ Testing procedure: SMT Tested by (name + signature).....: Approved by (+ signature).....: Supervised by (+ signature) .....: Testing location/ address.....:	N/A
☐ Testing procedure: RMT Tested by (name + signature).....: Approved by (+ signature).....: Supervised by (+ signature) .....: Testing location/ address.....:	N/A

帝迈生物 DYMIND BIOTECH

Usability checklist

Summary of testing:	
Tests performed (name of test and test clause): All clause of standard.	**Testing location:** Shenzhen Dymind Biotechnology Co., Ltd.. 10th Floor, Building B, High-tech park,Guangqiao Road, Tianliao Community,Yutang Street, Guangming District, Shenzhen, 518107, P.R.China
Summary of compliance with National Differences: List of countries addressed: N/A ☒ The product fulfils the requirements of IEC 62366-1:2015	
Copy of marking plate The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.	

帝迈生物 DYMIND BIOTECH

Usability checklist

Test item particulars.....:			
Classification of installation and use……:	N/A		
Supply connection ……:			
Context of Use ……:			
Abbreviations used in the report:			
- Usability Engineering:	UE	- Risk analysis:	RA
- User interface:	UI	- Risk management:	RM
- Primary operating function:	POF		
Possible test case verdicts:			
- test case does not apply to the test object.....:	N/A		
- test object does meet the requirement.....:	Pass (P)		
- test object does not meet the requirement.....:	Fail (F)		
Testing:			
Date of receipt of test items……:	2021-1-04		
Date(s) of performance of tests.....:	2021-01-05 to 2021-04-17		

General remarks:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.

"(see Enclosure #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
Throughout this report, a point (coma) is used as the decimal separator.

List of test equipment must be kept on file and available for review.

This Test Report contains the general safety requirements as related to the usability of Medical Equipment.

Name and address of factory (ies) : Shenzhen Dymind Biotechnology Co., Ltd.

10th Floor, Building B, High-tech park,Guangqiao Road, Tianliao Community,Yutang Street, Guangming District, Shenzhen, 518107, P.R.China

General product information:

The SARS-CoV-2 Antigen Test Kit is a gold immuno-chromatographic assay (GICA) that is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in, nasal (NS) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider.
The SARS-CoV-2 Antigen Test Kit does not differentiate between SARS-CoV and SARS-CoV-2.
Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.
This product is suitable for self-use only. People with visual impairment need to use it with the help of

others. Sampling of persons under 15-year-old should be carried out under adult supervision. People over seventy years should be supported in the recruitment process.
Please follow the instruction for use, and rinse your mouth with water 30 minutes before sampling, and do not eat, smoke, drink alchol or drink after rinsing.

4	**GENERAL REQUIREMENTS**		
4.1	General Requirements		P
4.1.1	USABILITY ENGINEERING PROCESS		P
	Has the MANUFACTURER established, documented and maintained a USABILITY ENGINEERING PROCESS to provide SAFETY for the PATIENT, USER and others related to USABILITY for the product?	DMR003-CE-001A V1.0 Instruction for Use DMR003-CE-002A V1.0 Risk Management report DMR003-CE-004A V1.0 Performance Characteristics DMR003-CE-005A V1.0 Clinical Evaluation	P
	Does the process addressed USER INTERACtions with the medical device according to the ACCOMPANYING DOCUMENT including, but not limited to transport, storage, installation, operation, maintenance, repair and disposal?	DMR003-CE-001A V1.0 Instruction for Use	P
4.1.2	RESIDUAL RISK		P
	ARE RESIDUAL RISKS ASSOCIATED WITH USABILITY OF THE MEDICAL DEVICE PRESUMED TO BE ACCEPTABLE, UNLESS THERE IS OBJECTIVE EVIDENCE TO THE CONTRARY AND DOCUMENTED?	DMR003-CE-002A V1.0 Risk Management report	P
4.1.3	INFORMATION FOR SAFETY		P
	Manufacturer subject the information for safety used asa risk control to the usability engineering process (e.g.,warnings or limitation of use in the accompanying documents, marking, etc.) in the ue file and accompanying documents.	DMR003-CE-001A V1.0 Instruction for Use DMR003-CE-002A V1.0 Risk Management report DMR003-CE-007A V1.0 Label Introduce for use	P
	Disregarding such information for safety is considered beyond any further reasonable means of risk control	DMR003-CE-001A V1.0 Instruction for Use DMR003-CE-002A V1.0 Risk Management report	P
4.2	USABILITY ENGINEERING FILE		P
	The results of the USABILITY ENGINEERING PROCESS are recorded in the usability engineering file	DMR003-CE-002A V1.0 Risk Management report	P

	The records and other documents that make up the USABILITY ENGINEERING FILE form part of other documents and files (e.g., a MANUFACTURER'S product design file or RISK MANAGEMENT FILE), (SEE List of documents make up the UE file)	SEE list of documents make up the UE file.	P
4.3	Tailoring of the USABILITY ENGINEERING effort		P
	THE USABILITY ENGINEERING PROCESS IS SCALEDBASED ON THE SIGNIFICANCE OF ANY MODIFICATIONS DEPENDING ON THE RESULTS OF THE RISK ANALYSIS AND DOCUMENTED	DMR003-CE-002A V1.0 Risk Management report	P

5	**USABILTY ENGINEERING PROCESS**		P
5.1	Application specification		P
	APPLICATION OF MEDICAL DEVICE IN THE USABILITY ENGINEERING FILE IS SPECIFIED BY THE MANUFACTURER AND INCLUDES	/	/
	– intended medical indication (e.g., conditions(s) or disease(s) to be screened, monitored, treated, diagnosed, or prevented);	DMR003-CE-001A V1.0 Instruction for Use: Intended Use	P
	– intended patient population (e.g., age, weight, health, condition);	DMR003-CE-001A V1.0 Instruction for Use: Intended Use	P
	– intended part of the body or type of tissue applied to or interacted with;	DMR003-CE-001A V1.0 Instruction for Use : Intended Use	P
	– intended conditions of use (e.g..Environment including hygienic requirements, frequency of use, location, mobility);and	DMR003-CE-001A V1.0 Instruction for Use : Storage And Stability Limitaions	P
	– operating principle(s)	DMR003-CE-001A V1.0 Instruction for Use	P
5.2	Frequently used functions		P
	Are frequently used functions that involve user interaction with the medical device are determined and recorded in the usability engineering file?	DMR003-CE-001A V1.0 Instruction for Use : DMR003-CE-007A V1.0 Label Introduce for use	P

5.3	Identification of hazards and hazardous situations related to usability		P
5.3.1	Identification of characteristics to safety		P
	Identification of characteristics related to safety (part of a risk analysis) that focuses on usability performed according to ISO 14971:2012, 4.2.	DMR003-CE-002A V1.0 Risk Management report	P
	– application specification, including user profile(s); and –frequently used functions.	DMR003-CE-002A V1.0 Risk Management report	P
	Results of this identification characteristics related to safety recorded in the usability engineering file	DMR003-CE-002A V1.0 Risk Management report	P
5.3.2	Identification of known or foreseeable hazards and hazardous situations		P
	Manufacturer has identified known or foreseeable hazards (part of a risk analysis) related to usability according to ISO 14971:2009, 4.3.	DMR003-CE-002A V1.0 Risk Management report	P
	Identification of hazards considered hazards to patients, users and other persons	DMR003-CE-002A V1.0 Risk Management report	P
	Reasonably foreseeable sequences or combinations of events involving the user interface that can result in a hazardous situation associated with the medical device were identified. the severity of the resulting possible harm is determined.	DMR003-CE-002A V1.0 Risk Management report	P
	During the identification of hazards and hazardous situations, the following was considered: – application specification, including user profile(s); – task related requirements; – context of use; – information on hazards and hazardous situations known for existing user interfaces of medical devices of a similar type, if available; – preliminary use scenarios; – possible use errors; – if an incorrect mental model of the operation of the medical device can cause a use error resulting in a hazardous situation;and – results of the review of the user interface The results of this identification of hazards, hazardous situations and severity are recorded in the usability engineering file.	DMR003-CE-002A V1.0 Risk Management report	P
5.4	Primary operating functions		P
	The manufacturer has determined the primary operating functions and recorded in the usability engineering file	DMR003-CE-001A V1.0 Instruction for Use ; Test Procedure	P

	The inputs to the primary operating functions include frequently used functions and functions related to safety of the medical device	DMR003-CE-001A V1.0 Instruction for Use ; Test Procedure DMR003-CE-002A V1.0 Risk Management report	P
5.5	Usability specification		P
	Manufacturer developed a usability specification recorded in the usability engineering file as part of the usability engineering process	DMR003-CE-001A V1.0 Instruction for Use DMR003-CE-002A V1.0 Risk Management report	P
	The usability specification recorded in usability engineering file. The usability specification may be integrated into other specifications	DMR003-CE-001A V1.0 Instruction for Use DMR003-CE-002A V1.0 Risk Management report	P
	The usability specification includes: – application specification; – primary operating functions – hazards and hazardous situations related to the usability; and – known or foreseeable use errors associated with the medical device	DMR003-CE-001A V1.0 Instruction for Use DMR003-CE-002A V1.0 Risk Management report	P
	The usability specification describes at least:	DMR003-CE-001A V1.0 Instruction for Use DMR003-CE-002A V1.0 Risk Management report	P
	– use scenarios related to the primary operating functions equipment, including – frequent use scenarios, and – reasonably foreseeable worst case use scenarios;	DMR003-CE-001A V1.0 Instruction for Use DMR003-CE-002A V1.0 Risk Management report	P
	– user interface requirements for the primary operating functions equipment including those to mitigate risk;	DMR003-CE-001A V1.0 Instruction for Use DMR003-CE-002A V1.0 Risk Management report	P
	– requirements for determining whether primary operating functions are easily recognizable by the user.	DMR003-CE-001A V1.0 Instruction for Use DMR003-CE-002A V1.0 Risk Management report	P
5.6	Usability validation plan		

	The manufacturer has developed and maintains a usability validation plan specifying:	DMR003-CE-003A-03 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing Usability engineering file DMR003-CE-003A-04 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing usability checklist	P
	– any method used for validation of the usability of the primary operating functions;	DMR003-CE-003A-03 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing Usability engineering file DMR003-CE-003A-04 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing usability checklist	P
	– the criteria for determining successful validation of the usability of the primary operating functions based on the usability specification; and	DMR003-CE-003A-03 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing Usability engineering file DMR003-CE-003A-04 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing usability checklist	P
	– the involvement of representative intended users	DMR003-CE-003A-03 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing Usability engineering file DMR003-CE-003A-04 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing usability checklist	P
	Usability validation performed in a laboratory setting	DMR003-CE-003A-03 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing Usability engineering file DMR003-CE-003A-04 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing usability checklist	P

	Usability validation performed in a simulated use environment	DMR003-CE-003A-03 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing Usability engineering file DMR003-CE-004A V1.0 Performance Characteristics	P
	Usability validation performed in the actual use environment	DMR003-CE-003A-03 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing Usability engineering file DMR003-CE-004A V1.0 Performance Characteristics DMR003-CE-005A V1.0 Clinical Evaluation	P
	The usability validation plan addresses: – frequent use scenarios, and – reasonably foreseeable worst case use scenarios That are identified in the usability specification	DMR003-CE-003A-03 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing Usability engineering file DMR003-CE-003A-04 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing usability checklist DMR003-CE-004A V1.0 Performance Characteristics DMR003-CE-005A V1.0 Clinical Evaluation	P
	The usability validation plan recorded in the usability engineering file	DMR003-CE-003A-03 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing Usability engineering file	P
5.7	User interface design and implementation		P
	Manufacturer designed and implemented the user interface as described in the usability specification utilizing, as appropriate, usability engineering methods and techniques	DMR003-CE-001A V1.0 Instruction for Use	P
5.8	Usability verification		P
	Manufacturer verified the implementation of the medical device user interface design according to the usability specification	DMR003-CE-004A V1.0 Performance Characteristics	

	The results of the verification are recorded in usability engineering file	DMR003-CE-004A V1.0 Performance Characteristics	P
5.9	Usability validation		P
	The manufacturer has validated the usability of the medical device according to the usability validation plan	DMR003-CE-005A V1.0 Clinical Evaluation	P
	The results are recorded in the usability engineering file	DMR003-CE-005A V1.0 Clinical Evaluation	P
	For the acceptance criteria documented in the usability validation plan that are not met: - further user interface design and implementation activities are performed; or - if further improvement is not practicable, the manufacturer may gather and review data And literature to determine if the medical benefits of the intended use outweigh the risk Arising from usability problems To perform this step, the manufacturer needs to estimate the risk arising from usability problems.	DMR003-CE-001A V1.0 Instruction for Use DMR003-CE-002A V1.0 Risk Management report DMR003-CE-005A V1.0 Clinical Evaluation	P
5.10	Questionnaire survey		P
	The manufacturer evaluates the usability of the product by obtaining feedback information from users after using the product through questionnaire survey.	DMR003-CE-003A-03 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing Usability engineering file	P
	The questionnaire includes age, gender, occupation, feedback in the process of product use and so on.	DMR003-CE-003A-03 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing Usability engineering file	P
	The manufacturer has collected the information obtained from the questionnaire survey and concluded that the product is suitable for people of different age (adolescents ages from 2-17, adults ages from 18-60, senior person ages over 60),education (primary school, high school, bachelor and master) , gender (female and male), occupation (driver, teacher, student, lawyer, accountant, officer, police, worker and so on),meets the needs of the product for self-use.	DMR003-CE-003A-03 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing Usability engineering file DMR003-CE-003A-04 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing usability checklist	P

6	Accompanying documents		P

	The accompanying document includes a summary of the medical device application specification	DMR003-CE-001A V1.0 Instruction for Use DMR003-CE-007A V1.0 Label Introduce for use	P
	A concise description of the medical device, its operating principles, significant physical and performance characteristics and intended user profile are included in the accompanying document	DMR003-CE-001A V1.0 Instruction for Use DMR003-CE-007A V1.0 Label Introduce for use	P
	The accompanying document is written at a level consistent with the intended operator profile	DMR003-CE-007A V1.0 Label Introduce for use	P
	The accompanying document is written at a level consistent with the intended operator profile	DMR003-CE-001A V1.0 Instruction for Use	P
	The accompanying document for equipment are, optionally, provided electronically	N/A, the accompanying documents for equipment aren't provided electronically.	N/A
	Usability engineering process includes the information that will need to be provided as a hard copy or as markings on medical device when accompanying documents are provided electronically	N/A, the accompanying documents for equipment aren't provided electronically	N/A

7	Training and materials for training		N/A
	The required training on the medical device for safe and effective use of primary operating functions by the intended user is given by:	N/A, the manufacturer does not provide training.	N/A
	– necessary training materials provided by the manufacturer;	N/A, the manufacturer does not provide training.	N/A
	– necessary training materials are available; or	N/A, the manufacturer does not provide training.	N/A
	– the manufacturer provides training	N/A, the manufacturer does not provide training.	N/A
	The accompanying document describes the available training options (recommendation: accompanying document include the suggested duration and frequency of such training)	N/A, the manufacturer does not provide training.	N/A
	Intended use and user profile(s) are the basis for training and training material	N/A, the manufacturer does not provide training.	N/A

List of documents make up the UE file	

No.	Document title
1	DMR003-CE-001A V1.0 Instruction for Use
2	DMR003-CE-002A V1.0 Risk Management report
3	DMR003-CE-004A V1.0 Performance Characteristics
4	DMR003-CE-005A V1.0 Clinical Evaluation
5	DMR003-CE-007A V1.0 Label Introduce for use
6	DMR003-CE-003A-03 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing Usability engineering file
7	DMR003-CE-003A-04 V1.0 SARS-CoV-2 Antigen Test Kit Self-testing usability checklist
supplementary information: N/A	