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Project Name:

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

Document Name:

Risk Management report

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RISK MANAGEMENT REPORT

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1. Foreword

This article is prepared for the risk management of SARS-CoV-2 Antigen Test Kit (Colloidal Gold). Overall known or foreseeable hazards and the potential causes of each hazard are identified in the article. Furthermore, severity and probability of occurrence of each hazard are estimated. The necessary risk control measures must be taken to the risks which are not acceptable. Residual risk level must be evaluated after risk control measures have been taken.

Result: Not only the individual risk but also the overall risks can be reduced to an acceptable level through proper control measures.

2. Purpose

The purpose of this risk management is to assess the risks may arise by SARS-CoV-2 Antigen Test Kit (Colloidal Gold) which has been put into production. In order to control the risk in the acceptable level, an exposition is made of necessary measures relatively in this article. Risk management helps the company to adopt appropriate measures for the aim of improving product, advance product quality and meet the orders and potential demands of clients.

According to the requirements of EN ISO 14971:2019 and IVDD 98/79/EC and ISO/TR 24971:2020, Medical devices — Guidance on the application of ISO 14971:2019,to ensure the risk management report are compliance with IVDD essential requirement and seven difference. Perform overall evaluation on the risk management activities of each stage after the marketing of the product to ensure that the risk management plan has been satisfactorily completed, and confirm that the product risk has been managed and controlled within acceptable limits through the risk analysis, risk evaluation and risk control as well as the acceptability evaluation of the comprehensive residual risks.

3. Device Definition

3.1. Description of the Device

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.

3.2. Packaging Specification

SARS-CoV-2 Antigen Test Kit (Colloidal Gold) of different specifications have the same material composition, and the intended use and user population are the same, therefore the potential risks of SARS-CoV-2 Antigen Test Kit (Colloidal Gold) of different specifications are the same.

Specification: 1T/Kit, 6T/Kit, 20T/kit.

3.3. 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 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.

3.4. Components Description

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

3.5. Raw materials

1. Test Cassette
2. sample tube with extraction reagent 、 Nasal Swab
3. Instructions for use

3.6. Packaging and Shelf-life

SARS-CoV-2 Antigen Test Kit (Colloidal Gold) are packaged as follows:.
Carton, Specification: 1T/Kit, 6T/Kit, 20T/kit Shelf-life： 12 month

3.7. Warnings and 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. Sample collection and handling procedures don't require specific training and guidance. The operator should be able to read the instructions of use.

12.Rinse your mouth with water 30 minutes before sampling, and do not eat, smoke, drink alcohol or drinks after rinsing.

4. Reference

[1] EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

[2] IVDD 98/79/EC

[3] ISO/TR 24971:2020 Medical devices — Guidance on the application of ISO 14971

More details please refer to risk management plan

5. Risk management plan

5.1. Scope

This risk management report specifies a process for Manufacture. to identify the hazards associated with SARS-CoV-2 Antigen Test Kit (Colloidal Gold), to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

The requirements of the risk management report are applicable to all stages of the life-cycle of a medical device.

5.2. Requirements for review of risk management activities

The risk management plan details how and when these management reviews will occur for a specific medical device. The requirements for the review of risk management activities is part of the quality system review requirement.

Stage of life-cycle	Risk management process
Design and development planning	Preliminary Hazard Analysis
Design and development inputs	Identification of hazards
Design and development outputs	Estimation of the risks for each hazardous situation

Design and development verification	Risk evaluation
Design and development trial-produce	Risk mitigation and control
Design and development validation	Overall residual risk evaluation
Product realization	Production/Post-production information
Post-production	
Control of design and development changes	Risk evaluation
Post-production	Review of Post-production information

5.3. Criteria of Risk Evaluation

The criteria for risk acceptability are essential for the ultimate effectiveness of the risk management process. For each risk we choose appropriate risk acceptability criteria, which are determined according to our policy for determining criteria for risk acceptability and thus are based upon applicable national or regional regulations and relevant International Standards, and take into account available information such as the generally accepted state of the art and known stakeholder concerns.

5.3.1. **Severity Levels**

Evaluate the severity of mask harms based on the following sources of information

— published standards;

— scientific or technical investigations;

— field data from similar medical devices already in use, including publicly available reports of incidents;

— clinical evidence;

— adverse side effect database;

— expert opinion;

Risk evaluation team divide these estimates into five categories.

The risk evaluation team will involve into the risk management review activities.

No.	Severity	Description	Definition
1	Negligible	Inconvenience or temporary discomfort.	No complaint or complaints without request.
2	Minor	Results in temporary injury or impairment not requiring professional medical intervention.	Feedback of causation analysis and corrective (prevention) measures is required after complaints.
3	Serious	Results in injury or impairment requiring professional medical intervention.	Cause general compensation.
4	Critical	Results in permanent impairment or life-threatening injury,like causes irreversible damage to lung function to the user or be infected by others	Cause serious compensation.

5	Catastrophic	Results in patient death.	Cause major compensation results in company insolvency.

5.3.2. **Probability of Occurrence**

Evaluate the possibility of SARS-CoV-2 Antigen Test Kit (Colloidal Gold) harms based on the following sources of information

— use of historical design and development data;

— prediction of probabilities using analytical or simulation techniques;

— use of experimental data;

— reliability estimates;

— production and post-production information;

— use of expert judgment

Risk evaluation team divide these estimates into five categories.

No.	Common terms	Description (the ratio between number of events and sales of this product within a year)
1	Improbably	$<10^{-6}$
2	Remote	$<10^{-5}$ and $\geqslant 10^{-6}$
3	Occasional	$<10^{-3}$and $\geqslant 10^{-4}$
4	Probable	$<10^{-2}$and $\geqslant 10^{-3}$
5	Frequent	$\geqslant 10^{-2}$

5.3.3. **Criteria for Risk Acceptability**

Risk Acceptability					
Severity / probability	Negligible1	Minor2	Serious3	Critical4	Catastrophic5
Frequent5	NAC	NAC	NAC	NAC	NAC
Probable4	NAC	NAC	NAC	NAC	NAC
Occasional3	AC	AC	NAC	NAC	NAC
Remote2	AC	AC	AC	NAC	NAC
Improbable1	AC	AC	AC	AC	NAC

NAC=not acceptable

AC=acceptable

All risks estimated for each harm must be recorded in column "RL" of the section 7 tablet form with range

level (AC/NAC) per criteria defined in the table above, and described separately whether control measures are available.

Only when risks meet the relevant EU standards or is consistent with the current mainstream marketed products（state of the art）, the risks will be judged in acceptable area.

5.4. Methods of obtaining relevant post-production information

The methods of obtaining post-production information are part of the established quality management system procedures at Manufacture., which includes:

<Advise notice and adverse event report procedure>

<Customer feedback management procedure>

Our manufacture has established generic procedures to collect information from various sources While a reference to the quality management system procedures can suffice in most cases, any product-specific requirements can be directly added to the risk management plan. The risk management plan includes documentation of decisions, based on a risk analysis, about what sort of post-market surveillance is appropriate for the device, for example, whether reactive surveillance is adequate or whether proactive studies are needed. Details of clinical studies envisaged should be specified.

6. Risk analysis

6.1. Risk Analysis Process

Risk analysis is performed for SARS-CoV-2 Antigen Test Kit (Colloidal Gold) as described in 7.2 to 7.4. It includes intended use and identification of characteristics related to the safety of the medical device, identification of hazards and estimation of the risks for each hazardous situation. The implementation of the planned risk analysis activities and the results of the risk analysis are recorded in the risk management file.

Similar medical device information is used in the process and between SARS-CoV-2 Antigen Test Kit (Colloidal Gold) and similar medical device whether these introduce new hazards or significant differences in outputs, characteristics, performance, or results.

There are two risk analysis technique are used in this process, which are design Failure Mode and Effects Analysis (DFMEA）and process Failure Mode and Effects Analysis (PFMEA）.

In addition to the records required in7.2 to 7.4, the documentation of the conduct and results of the risk analysis include the following.

A) Description and identification of SARS-CoV-2 Antigen Test Kit (Colloidal Gold)

The kits come in two sizes, but the materials, uses, and compliance are all the same, so the risks are the same

B) Scope and date of the risk analysis

The risk management report includes all stages of the life-cycle of a medical device including verification and evaluation process.

Stage of life-cycle	Risk management process
Design and development planning	Preliminary Hazard Analysis

Design and development inputs	Identification of hazards
Design and development outputs	Estimation of the risks for each hazardous situation
Design and development verification	Risk evaluation
Design and development trial-produce	Risk mitigation and control
Design and development validation	Overall residual risk evaluation
Product realization	Production/Post-production information
Post-production	
Control of design and development changes	Risk evaluation
Post-production	Review of Post-production information

6.2. Intended Use and identification of Characteristics Related to the Safety of the Medical Device

We document the intended use and reasonably foreseeable misuse for SARS-CoV-2 Antigen Test Kit (Colloidal Gold).

① The following questions can aid the person in identifying all the characteristics of the medical device that could affect safety.

No	Characteristics related to the safety of product	A	NA	If applicable, please elaborate	Possible hazard
1	What is the intended use and how is the medical device to be used?	√		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. 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	Operational hazards

No	Characteristics related to the safety of product	A	NA	If applicable, please elaborate	Possible hazard
				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-test only.People with visual impairmentneed to use it with the help of others.	
2	Is the medical device intended to be implanted?		√	The product is not implanted device	
3	Is the medical device intended to be contact with the patient or other person?	√		Indirect contact with protective operation staff.	Chemical hazard Operational hazards

No	Characteristics related to the safety of product	A	NA	If applicable, please elaborate	Possible hazard
4	What material or components are utilized in medical device or are used with, or are in contact with, the medical device?	√		Indirect contact with protective operation staff.	Biological hazards Operational hazards
5	Is energy delivered to or extracted from the patient?		√	The product is no energy delivered	
6	Are substances delivered or extracted from the patient?		√	Sample collection from patients	Operational hazards Information hazards
7	Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?		√	The product have no such process.	
8	Is medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	√		Sterilization product	Chemical hazards Biological hazards

No	Characteristics related to the safety of product	A	NA	If applicable, please elaborate	Possible hazard
9	Is the medical device intended to be routinely cleaned and disinfected by the user?		√	The product are single use.	
10	Is the medical device intended to modify the patient environment?		√	This is not applicable for the device	
11	Are measurements taken?	√		The diagnostic conclusion need to be interpreted	Operational hazards Information hazards
12	Is the medical device interpretative?	√		The diagnostic conclusion need to be interpreted	Operational hazards Information hazards
13	Is the medical device intended for use in conjunction with other medical device, medicines or other medical technologies?		√	No, naked eye can directly observe the results, this product is only suitable for non-professionals.People with visual impairments need help to use it.	Operational hazards Information hazards
14	Are there unwanted outputs of energy or substances?		√	This is not applicable for the device	

No	Characteristics related to the safety of product	A	NA	If applicable, please elaborate	Possible hazard
15	Is the medical device susceptible to environmental influences?		√	Yes, Rough handling during transportation may cause breakage of outer garment and breakage of the package. And the raw materials of the product are medical materials, the packaging materials have been verified by simulated transport, the temperature and humidity are required during storage.	Biological hazards, Chemical hazards, Clinical hazards
16	Dose the medical device influence the environment?		√	Yes, the product may influence the environment, it should be disposed as medical waste in accordance with local regulation.	Environmental hazards
17	Are there essential consumables or accessories associated with the medical device?		√	This is not applicable for the device	
18	Is maintenance or calibration necessary?		√	This is not applicable for the device	
19	Does the medical device contain software?		√	No, naked eye can directly observe the results, this product is only suitable for non-professionals.People with visual impairments need help to use it.	Information hazards
20	Dose the medical device have a restrict shelf-life?	√		Yes, Store kit components at 2-30℃, out of direct sunlight. Kit components are stable until the expiration date printed on the outer box.	Biological hazards

No	Characteristics related to the safety of product	A	NA	If applicable, please elaborate	Possible hazard
21	Are there any delayed or long-term use effects?		√	This is not applicable for the device	
22	To what mechanical force will the medical device be subjected?		√	This is not applicable for the device	
23	What determines the lifetime of the medical device?	√		Yes, Product materials, packaging materials determine the life of the product.	Bacteria hazards Operational hazards Clinical hazards
24	Is the medical device intended for single use?	√		Single use.	Biological hazards
25	Is safe decommissioning or disposal of the medical device necessary?	√		Safe disposal of products after use to avoid environmental hazards.。	Bacteria hazards Biological hazards Environmental hazards
26	Dose installation or use of the medical device requires special training or special skills?	√		refer to user manual .	Operational hazards Information hazards

No	Characteristics related to the safety of product	A	NA	If applicable, please elaborate	Possible hazard
27	How will information for safe use be provided?	√		Labels and instruction manual show the information for safe use.	Operational hazards Information hazards
28	Will new manufacturing processes need to be established or introduced?		√	This is not applicable for the device	
29	Is successful application of the medical device critically dependent on human factors such as the user interface?	√		Yes, the operation need dependent on human factors.	Operational hazards Information hazards
30	Does the medical device use an alarm system?		√	This is not applicable for the device	
31	In what way(s) might the medical device be deliberately misused?	√		The medical device might be deliberately misused by not strictly following the instruction for use.	Operational hazards
32	Does the medical device hold data critical to patient care?		√	This is not applicable for the device	
33	Is the medical device intended to be mobile or portable?		√	This is not applicable for the device	

No	Characteristics related to the safety of product	A	NA	If applicable, please elaborate	Possible hazard
34	Does the use of the medical device depend on essential performance?	√		the essential performance determines the safety and effectiveness of the product.	Clinical hazards
35	Does the medical device have a degree of autonomy?		√	This is not applicable for the device	
36	Does the medical device produce an output that is used as an input in determining clinical action?	√		Yes, the results will be a output for diagnostic conclusion.	Information hazards Clinical hazards

② The reasonably foreseeable misuse listed as below table 1.

6.3. Identification of Hazards and Hazardous Situation

According to the experience with the same and similar types of device, publications and other available sources, the documentation on known and foreseeable hazards associated with SARS-CoV-2 Antigen Test Kit (Colloidal Gold) in both normal and fault conditions are compiled in section 7.5.

6.4. Estimation of the Risks for Each Hazardous Situation

Reasonably foreseeable sequences or combinations of events that can result in a hazardous situation have been considered and the resulting hazardous situations have been recorded in section 7.5:

6.5. Identify the risk and hazard, hazard situation

The source of risk come from product life-cycle, base on risk analysis technique (DFMEA and PFMEA), which include product design, manufacturing process, operation process. The details shown in the below table1:

Table1: Preliminary Hazard Analysis Form

Hazard number	Hazard Type	Foreseeable sequence of events	Hazard situation	Harm	Control measures
H1	Information hazard	User Manual information is not complete	User professional misuses the product	Invalid function, inconvenient to use	Indicate usage and precautions in the manual See Instruction for Use
H2	Information hazard	Intended use statement and disclosure of defects are inadequate	User professional uses the product if it is not applicable	Invalid function, inconvenient to use	Indicate the product's intended use in the manual See Instruction for Use
H3	Information hazard	Operating instructions are too complicated	Userl staff cannot understand, and use the product incorrectly	The diagnostic results are not precisely.	The operating instructions are simple in language and the steps are clear and easy to understand.
H4	Information hazard	Insufficient warning of side effects in specification	User professional uses the product if it is not applicable	Unexpected side effect happen to patients.	The manual gives full warning to the side effects of the product See Instruction for Use: SPECIMEN COLLECTION AND PREPARATION
H5	Information hazard	Insufficient warnings about the hazards of possible reuse of disposable medical devices	The product effectiveness have been affected.	The diagnostic results are not precisely.	The manual and labels indicate that the product is for single use. Provide adequate warnings about the hazards of reuse.

Hazard number	Hazard Type	Foreseeable sequence of events	Hazard situation	Harm	Control measures
H6	Information hazard	User Interpretation for Test Results error	The Interpretation for test Results error will induce diagnostic conclusion error.	diagnostic conclusion error may cause patients miss the applicable treatment and infect other people and cause pandemic.	Train users and explain the test results in detail in the instruction manual. See Instruction for Use: INTERPRETATION OF TEST RESULTS
H7	Operation hazards	Missing or degraded product function	Product function is defective	The diagnostic results are not precisely.	Perform design verification of key product components and control during production
H8	Operation hazards	The operator is not focused and forgotten (misremembered)	User misuses the product	The diagnostic results are not precisely.	Require the user to read the instruction and follow the instructions
H9	Operation hazards	The user interface usability is not well established.	User wrongly use the procedure of product.	The improper procedure may make the results not precisely.	The product usability test have been conducted.
H10	Operation hazards	Sample collection method are not follow the procedure.	Uncontrolled Sample collection method will affect following test.	The improper procedure may make the results not precisely.	Sample collection methods have been validated and are detailed in the instruction manual.
H11	Operation hazards	Sample stability	Sample storage, transportation environment or temperature, storage time could affect the test results.	Unstable sample may make the results not precisely.	Sample stability verification.

Hazard number	Hazard Type	Foreseeable sequence of events	Hazard situation	Harm	Control measures
H12	Operation hazards	In-use time exceed the defined shelf life.	If the reagent have been opened and in use time exceed the shelf life, the reagent kit will be dysfunction.	The dysfunction reagent may make the results not precisely.	Stability test could been conducted.
H13	Operation hazards	The test specimens involved in this kit should be considered as infectious substances,	If the test specimens touch the unprotected operation user. It may cause infection.	The test specimens is infectious substances, may cause operator infection.	Waste must be disposed of in accordance with local regulations
H14	Biological hazard	Storage temperature are out of suggest limit.	The temperature unnormal will affect the reagent and cause the materials dysfunction	The diagnostic results are not precisely.	Product storage temperatures are stated in the user's manual
H15	Biological hazard	Transportation temperature or cooling chain are out of range of temperature.	The temperature unnormal will affect the reagent and cause the materials dysfunction	The diagnostic results may be not precisely.	The transportation verification test should be conducted.
H16	Biological hazard	The product storage time exceed the defined shelf life.	The overdue reagent will affect the reagent and cause the materials dysfunction	The diagnostic results may be not precisely.	Stability verification tests shall be conducted and indicated in the specification
Hazard number	**Hazard Type**	**Foreseeable sequence of events**	**Hazard situation**	**Harm**	**Control measures**

H17	Biological hazard	The product have been explored to sunlight	The overdue reagent will affect the reagent and cause the materials dysfunction	The diagnostic results may be not precisely.	See Instruction for Use：STORAGE AND STABILITY
H18	Biological hazard	Package damaged	The damaged package have no function to protect outside substance and interference the detection.	The diagnostic results may be not precisely.	The packaging verification test have been conducted. The damaged package should not be used. The waring information indicated in specification
H19	Biological hazard	Interference substance exist during detection.	Interference substance exist will affect the analysis results.	The final diagnostic results may be not precisely.	Interference substance verification have been conducted. See Instruction for Use：ANALYTICAL PERFORMANCE
H20	Biological hazard	Non-conforming products have been issued into market.	Non-conforming products release to market could let patients using NC product.	The diagnostic results may be not precisely.	The QC and final inspection will check before Non-conforming product issued.
H21	Chemical hazard	Residual substances exceed standard requirements	Patient is given toxic substances	Allergies or other symptoms of infection	Test for product residues and protect operation user with cloths and glove and biosafety cabinet
H22	Chemical hazard	Chemical toxicity	Operation user use products with biocompatibility issues	Allergies or other symptoms of infection	protect operation user with cloths and glove and biosafety cabinet
H23	Clinical hazard	False positive results for diagnostic conclusion	the test results have rare results show false positive results.	The false positive results make patients panic and take necessary treatment.	Conduct clinical performance validation.
Hazard number	**Hazard Type**	**Foreseeable sequence of events**	**Hazard situation**	**Harm**	**Control measures**

H24	Clinical hazard	False negative results for diagnostic conclusion	The test results have rarely shown false positives.False negative results may occur when SARS-CoV-2 surface sites are mutated or otherwise altered.	The patients who got false negative results for diagnostic conclusion will miss the applicable treatment and infect other people and cause pandemic.	Conduct clinical performance validation.
H25	Biological hazard	Manufacturing production key process error.	The error manufacturing process will affect the final product functions	The diagnostic results may be not precisely.	The QC and final inspection will check before Non-conforming product issued. Operation staff need to be trained.
H26	Environment hazard	The disposable reagent and materials	The reagent and materials could be discard and do not follow the local country's regulation.	The disposable reagent and materials may contaminate environment hazard and hurt people.	Comply with local environmental laws and regulations.
H27	Environment hazard	The collection sample discard.	The collection samples could discard and do not follow the local country's regulation.	The disposable virus sample could infect other people.	Comply with local environmental laws and regulations.
H28	Clinical hazard	Misassembly of test strips during production	The test strip assembly process, the lack of marker components, the test strip into the card slot when the direction of the reverse..	The nonconformity product release to market will affect the diagnostic results interpretation.	1. Online QC 2. Training for operator 3. Recheck by operator 4. Quality test 5. Final product inspection
H29	Clinical hazard	Quality test operation error	The operator do not follow SOP to conduct quality test.	The quality test do not demonstrate functionality and let the nonconformity product release to market.	Training for operator Recheck by operator

H30	Operation hazards	For non-professionals: Nose swab	Overexertion may result in nasal damage	Affect customer operating experience	See DMR003-CE-001A V1.0 Instruction for Use ： SPECIMEN COLLECTION AND PREPARATION
H31	Information hazard	Observe test results	Observe the test results before the specified time	Easy to cause false negative results	SeeDMR003-CE-001A V1.0 Instruction for Use ： CDC Media/ Viral Transport Media Test Procedure:
H32	Information hazard	Determine the results	Not judging the results in the right way	Draw the wrong conclusions	SeeDMR003-CE-001A V1.0 Instruction for Use ： CDC Media/ Viral Transport Media Test Procedure:
H33	Information hazard	Observe test results	Observe the test results after the specified time	Easy to cause false Yang results	People with visual impairment need to use it with the help of others. SeeDMR003-CE-001A V1.0 Instruction for Use ： INTERPRETATION OF TEST RESULTS

7. Risk Evaluation

For each identified hazardous situation, we used the criteria defined in the risk management plan to evaluate each harm. Results of the risk evaluation are recorded in the risk management file in Appendix B: Risk management table

8. Risk Control

8.1. Risk Reduction

When risk reduction is required, risk control option analysis, implementation of risk control measures, residual risk evaluation, risk/benefit analysis, risk arising from risk control measures, and completeness of risk control activities are performed.

8.2. Risk Control Opting Analysis

Appropriate risk control measures are identified for reducing the risks to an acceptable level. The following risk control options are used in the priority order listed:

a) Protective measures in the medical device itself or in the manufacturing process;

b) Information for safety.

The risk control measures selected are recorded in the below tablet 2:

8.3. Implementation of Risk Control Measures

The risk control measures selected are implemented and the implementation of each risk control measure is verified. The verification is recorded in the risk management file. The effectiveness of the risk control measures is verified and the results are recorded in the risk management file in the below tablet 2:

Tablet 2: Risk Evaluation, Risk Control Measures and Residual Risk Versus Benefit Evaluation Record Sheet
*S represent Severity, P represent probability , level means risk accept level
* U means unacceptable risk
* A means acceptable risk

Hazard ID	Hazard type	Risk/harm estimation			Control measure	Implementation of verification	Risk/harm assessment after taking measures			Residual Risk evaluation	Risk Versus benefit evaluation
		S	P	level			S	P	level		
H1	Information hazard	S2	P3	A	Indicate usage and precautions in the manual	User manual information have been protocol and test with usability engineering file。	S2	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H2	Information hazard	S2	P3	A	Indicate the product's intended use in the manual	Design input and specification Usability test report	S2	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H3	Information hazard	S3	P3	U	The operating instructions are simple in language and the steps are clear and easy to understand.	Design input and specification Usability test report	S3	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H4	Information hazard	S4	P2	U	The manual gives full warning to the side effects of the product	Design input and specification Usability test	S4	P2	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.

						report Clinical evaluation report					
H5	Information hazard	S3	P3	U	The manual and labels indicate that the product is for single use. Provide adequate warnings about the hazards of reuse.	specification Usability test report Clinical evaluation report	S3	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H6	Information hazard	S4	P2	U	Training professional user and indicate detail interpretation for test results in specification.	specification usability validation. Clinical evaluation report Training user	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H7	Operation hazards	S4	P2	U	Perform design verification of key product components and control during production	Design verification report	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H8	Operation hazards	S3	P3	U	Require users to be professionally trained and follow the instructions.	specification usability validation. Clinical evaluation report Training user	S3	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H9	Operation hazards	S3	P4	U	The product usability test have been conducted.	specification Usability test report Clinical evaluation report Training user	S3	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.

H10	Operation hazards	S4	P2	U	Sample collection methods have been validated and specifications have been detailed.	Sample collection Usability test repor	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H11	Operation hazards	S4	P2	U	Sample stability verification.	Usability test report	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H12	Operation hazards	S4	P2	U	Stability test could been conducted.	Usability test report	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H13	Operation hazards	S4	P2	U	For non-professional users, the manual has been described in detail	The instructions	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H14	Biological hazard	S4	P2	U	Products are stored at 2-30 degrees Celsius and the storage temperature is indicated in the user manual stability test report	Usability test report	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H15	Biological hazard	S4	P2	U	The transportation verification test should be conducted.	specification and Usability test report	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H16	Biological hazard	S4	P2	U	The stability verification test should be conducted and indicated in specification and training the staff.	Transpiration verification report	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H17	Biological hazard	S4	P2	U	The information have been indicated in specification	Usability test report	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.

H18	Biological hazard	S4	P2	U	The packaging verification test have been conducted. The damaged package should not be used. The waring information indicated in specification	Packaging verification test report	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H19	Biological hazard	S4	P2	U	Interference substance verification have been conducted.	Interference substance verification report	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H20	Biological hazard	S4	P2	U	The QC and final inspection will check before Non-conforming product issued.	Final inspection SOP and the training report	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H21	Chemical hazard	S3	P3	U	Strictly follow the instructions to prevent accidents	. Dispose of waste in accordance with local regulations	S3	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H22	Chemical hazard	S3	P3	U	Strictly follow the instructions to prevent accidents	. Dispose of waste in accordance with local regulations	S3	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H23	Clinical hazard	S4	P2	U	Conduct clinical performance validation.	Clinical performance validation report	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H24	Clinical hazard	S4	P2	U	Conduct clinical performance validation.	Clinical performance validation report.	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H25	Clinical hazard	S4	P2	U	The QC and final inspection will check before Non-conforming product issued. Operation staff need to be trained.	Final inspection SOP and Operation staff training record	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.

H26	Environment hazard	S3	P3	U	The operator and staff have been trained with company' SOP and follow local country's environment regulation.	Operator training record	S3	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H27	Environment hazard	S4	P3	U	The operator and staff have been trained with company' SOP and follow local country's environment regulation.	Operator training record	S3	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H28	Clinical hazard	S4	P2	U	1.Online QC 2.Training for operator 3.Recheck by operator 4.Quality test 5.Final product inspection	Online QC record, operator training record, quality test record, final product inspection record.	S3	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H29	Clinical hazard	S4	P2	U	1.Training for operator 2.Recheck by operator	Operator training record.	S3	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H30	Operation hazards	S4	P2	U	See Instruction for Use: SPECIMEN COLLECTION AND PREPARATION	User manual information have been protocol and test with usability engineering file。	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H31	Information hazard	S4	P2	U	See Instruction for Use: CDC Media/ Viral Transport Media Test	User manual information have been protocol and	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.

					Procedure:	test with usability engineering file。					
H32	Information hazard	S4	P2	U	See Instruction for Use: CDC Media/ Viral Transport Media Test Procedure:	User manual information have been protocol and test with usability engineering file。	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.
H33	Information hazard	S4	P2	U	People with visual impairment need to use it with the help of others. See Instruction for Use: INTERPRETATION OF TEST RESULTS	User manual information have been protocol and test with usability engineering file。	S4	P1	A	The residual risk are acceptable	The benefits outweigh the risks, and the risks are acceptable.

8.4. Residual Risk Evaluation

After the risk control measures are applied, any residual risk will be evaluated using the criteria defined in the risk management plan. The results of the evaluation are recorded in the risk management file in the below tablet.

Only when residual risks meet the relevant EU standards or is consistent with the current mainstream marketed products（state of the art）, the residual risks will be judged acceptable.

8.5. Risk/Benefit Analysis

The residual risk is judged acceptable using the criteria established in the risk management plan and risks are outweighed by the benefits. Necessary information is decided for safety to disclose the residual risk. The results of the evaluation are recorded in the risk management file. After all Risk Controls have been implemented and verified, all risks are reduced to as low as possible. Individual and overall residual risks are acceptable. Mitigation methods didn't cause new risks. The manufacturer has established and maintained a systematic procedure to review information gained about the medical device or similar devices in the post-production phase. The judgment on overall residual risks is conducted and final conclusion is positive. The collection of post-production information is defined as using the customer feedback procedure of the organization, and update risk management of the product as needed. The whole process deemed in compliance with the requirements of standard EN ISO 14971:2019.

8.6. Risk Arising from Control Measures

There is no new risk arising from risk control measures.

8.7. Completeness of Risk Control

The risks from all identified hazardous situations have been considered. The results of this activity are recorded in the risk management file in Appendix B: Risk management table

9. Evaluation of Overall Residual Risk Acceptability

After all risk control measures have been implemented and verified, the overall residual risk posed by the medical device is acceptable using the criteria defined in the risk management plan.

Overall residual risk evaluation is the point where residual risk is viewed from broad perspective. Overall residual risk evaluation is performed by persons with the knowledge, experience, and authority to perform such tasks described in the risk management plan.

It involves application specialists with knowledge of and experience with the medical device. Review of warnings and operating instructions were selected to disclose overall residual risk. For details please refer to Appendix B.

Before the risk methods are taken:

	S1	S2	S3	S4	S5
P5	0	0	0	0	0
P4	0	1	1	0	0
P3	0	2	8	1	0
P2	0	0	0	25	0
P1	0	0	0	0	0

After the risk methods are taken:

	S1	S2	S3	S4	S5
P5	0	0	0	0	0
P4	0	0	0	0	0
P3	0	0	0	0	0
P2	0	0	0	0	0
P1	0	3	9	26	0

10. Production/Post-Production Information

A system is establishing, document and maintain to collect and review information about the medical device or similar devices in the production and the post-production phases. For details please refer to <Advise notice and adverse event report procedure> and <Customer feedback management procedure> at Manufacture, when establishing a system to collect and review information about the medical device, the following things are considered:

a) The mechanisms by which information generated by the operator, the user, or those accountable for the installation, use and maintenance of the medical device is collected and processed, and

b) New or revised standards; and

c) Design change; and

d) Change of material supplier or manufacture process.

The system can also collect and review publicly available information about similar medical devices on the market. The information will be evaluated for possible relevance to safety, especially the following:

----if previously unrecognized hazards or hazardous situations are present or;

----if the estimated risks arising from a hazardous situation are no longer acceptable.

If any of the above conditions occur:

1) The impact on previously implemented risk management activities shall be evaluated and shall be fed back as an input to the risk management process and;

2) A review of the risk management file for the medical device shall be conducted; if there is a potential that the residual risks or its acceptability has changed, the impact on previously

implemented risk control measures shall be evaluated. The results of this evaluation will be recorded in the risk management file.

3) Production and post-production information shall be collected, monitored and analyzed as per company's quality system procedures/work instructions and recorded in the appendix D: Production and post-production information Annual Risk Management

11. Results and Conclusion

The implementing of the risk management process is completely according to EN ISO 14971:2019. Although SARS-CoV-2 antigen detection kits (colloidal gold) are available in two sizes, given that their raw materials, intended use, and user population are consistent, the potential risks they have are also consistent.
The advantages of using SARS-CoV-2 Antigen Test Kit (Colloidal Gold) are obvious and its benefit is much greater than its risk. The residual risk and overall residual risk of the SARS-CoV-2 Antigen Test Kit (Colloidal Gold)are acceptable. Therefor the overall benefits over weigh the risks.

Appendix A: Evaluation of Overall Residual Risk Acceptability

1. General

After all risk control measures have been implemented and verified, the overall residual risk posed by SARS-CoV-2 Antigen Test Kit (Colloidal Gold) are acceptable using the criteria defined in the risk management plan. Overall residual risk evaluation is viewed from a broad perspective and performed by persons with the knowledge, experience, and authority to perform such tasks. It is involving application specialists with knowledge of and experience with SARS-CoV-2 Antigen Test Kit (Colloidal Gold).

Review for conflicting requirements, review of warnings, review of the operating instructions is choosing for evaluating overall residual risk.

The necessary information is included in the Labels and Instructions for Use to disclose the overall residual risk.

2. Information for safety

The information for safety and effectively is developed to provide to patients, users and others who will contact with the product. It is provided in labels and instructions for use which including an explanation of risk, the consequences of exposure and what should be done or avoided to prevent harm. In developing the information, the following have been considering:

---the level of priority appropriate to classify an action (warning, caution, etc.);
---the level or detail of information needed;
---the location for the information for safety (e.g. a warming label);
---the wording or pictures to be used to ensure clarity and understandability;
---the immediate recipients (e.g. users, service personnel, patients);
---the appropriate media for providing the information, (e.g. labels and instructions for use);
---regulatory requirement.

3. Disclosure of residual risks

When developing the disclosure of overall residual risks, the indication, instructions for use, contraindication, warning, storage and presentations are identified to be communicated and the medical staffer is directed in order to inform, motivate and enable the user to use the device safely and effectively.

According to examine the residual risks what should be disclosed is determined. The followings are considered:

---the level or detail needed;
---the wording to be used to ensure clarity and understandability;
---the immediate recipients (e.g. users, service personnel, installers, patients);
---the means/media to be used (e.g. labels and instructions for use on paper in package).