| Humasis® | Technical file<br>Humasis COVID-19 Ag Test<br>C. Result of risk analysis | Document No. | RN-20-004-H003 |
|---|---|---|---|
| | | Origin date | AUG 21. 2020 |
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This document was produced to certify the CE marking on the COVID-19 antigen test on the basis of "In Vitro Diagnostic Directive (98/79/EC)".



**Classification**

**EDMA code :** 15. 04. 80. 90. 00 (Other viral Antigen/ Antibody Detection)

*EDMA : European Diagnostic Manufacturers Association

**Conformity assessment route**

Annex IV-EC Declaration of Conformity(Full Quality Assurance ISO9001/EN ISO 13485)

**Rev. No. : 00 Effective date : AUG 21. 2020**

**Originated by :** 5.1.2e **Date :** 2020-08-21

**Reviewed by :** 5.1.2e **Date :** 2020-08-21

**Approved by :** 5.1.2e **Date :** 2020-08-21

**HUMASIS Co., Ltd.**

## Document History

*Confidential Documents*

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| Rev. No. | Date | PAGES | Contents | Prepared by |
|---|---|---|---|---|
| 00 | AUG 18. 2020 | 9 | The first issue | 5.1.2e |

## 1. Objective of risk analysis

The risk analysis report was prepared in an effort to investigate a safety of the Humasis COVID-19 Ag Test produced by Humasis Co., Ltd., and potential risk factors. The investigation was performed by the Quality Management Department of Humasis Co., Ltd. In accordance with IVDD 98/79/EC, EN ISO14971:2012 and EN 62366:2008

## 2. Overview of risk analysis

### 2.1. Products

Humasis COVID-19 Ag Test

### 2.2. A responsible person of risk analysis

5.1.2e

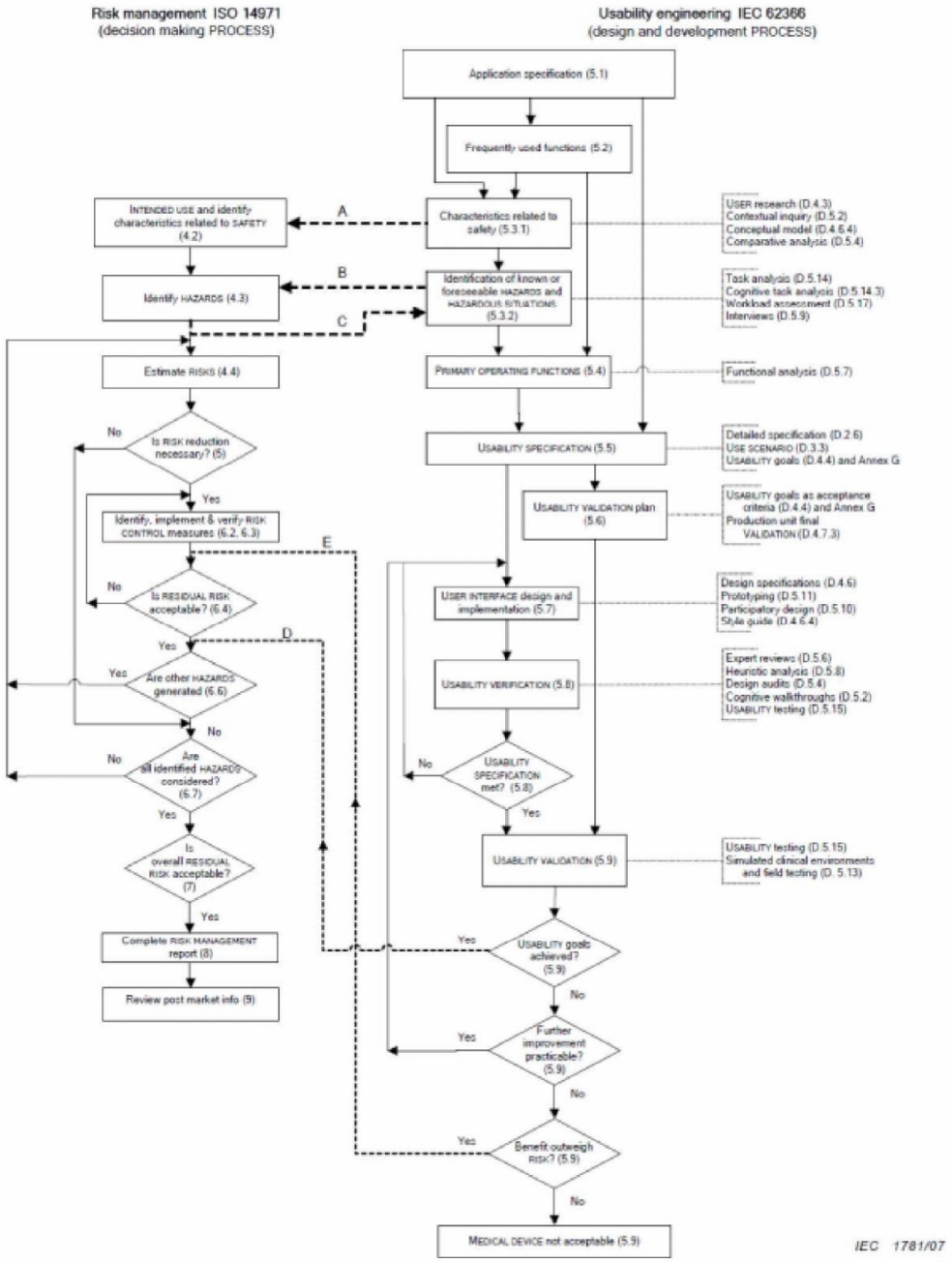
### 2.3. Date

2020.08.21

### 2.2. Standards

**EN ISO 14971: 2012** / Medical devices – Application of risk management to medical devices.
**EN 13641: 2002** / Elimination or reduction of risk of infection related to in vitro diagnostic reagents.
**EN 62366: 2008 /** Medical devices - Application of usability engineering to medical devices.
Our standard No. **Humasis-P-7021** / Process of risk management.
**Humasis-P-7025** / Process of usability engineering.

## 3. Flow chart of risk management



## 4. Questions

Annex A (EN ISO 14971:2012) give 32 questions for helping of risk analysis. 11 questions were added for application of usability (EN 62366:2008). The question can be used to identify medical device characteristics that could impact on safety. The answer for question is shown at table below.

| Section | Question | Answer |
|---|---|---|
| 1 | What is the intended use/intended purpose and how is the medical device to be used? | Detection of COVID-19 antigen in human nasopharyngeal swab specimen |
| 2 | Is the medical device intended to contact the patient or other persons? | Not Applicable |
| 3 | What materials and/or components are incorporated in the medical device or are used with, or are in contact with, the medical device? | Not Applicable |
| 4 | Is energy delivered to and/or extracted from the patient? | Not Applicable |
| 5 | Are substances delivered to and/or extracted from the patient? | Specimens are patient's blood |
| 6 | Are biological materials processed by the medical device for subsequent re-use? | Not Applicable |
| 7 | Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable? | Not Applicable |
| 8 | Is the medical device intended to be routinely cleaned and disinfected by the user? | Not Applicable |
| 9 | Is the medical device intended to modify the patient environment? | Not Applicable |
| 10 | Are measurements taken? | No. Humasis COVID-19 Ag Test is designed for the qualitative determination of COVID-19 antigen. |
| 11 | Is the medical device interpretative? | If the medical device show two line in test line and control line, it would be positive result and if the medical device show only one line at control region, it would be negative result. |
| 12 | Is the medical device intended for use in conjunction with medicines or other medical technologies? | Not Applicable |

| | | |
|---|---|---|
| 13 | Are there unwanted outputs of energy or substances? | Not Applicable |
| 14 | Is the medical device susceptible to environmental influences? | The medical device is sensitive to humidity when the test device opens from pouch. In sealing state of kit, it can be stored at room temperature or refrigerated. |
| 15 | Does the medical device influence the environment? | Not Applicable |
| 16 | Are there essential consumables or accessories associated with the medical device? | Not Applicable |
| 17 | Is maintenance and/or calibration necessary? | Not Applicable |
| 18 | Does the medical device contain software? | Not Applicable |
| 19 | Does the medical device have a restricted shelf-life? | The medical device has shelf-life for 18 months at 2~30℃ in initial sealing state |
| 20 | Are there any delayed and/or long-term use effects? | Not Applicable |
| 21 | To what mechanical forces will the medical device be subjected? | Not Applicable |
| 22 | What determines the life-time of the medical device? | Decreasing of the stability |
| 23 | Is the medical device intended for single use? | The medical device is intended for single use. |
| 24 | Is safe decommissioning or disposal of the medical device necessary? | The medical device needs special disposal. Because the medical device with unknown specimen is risk of infection. |
| 25 | Does installation or use of the medical device require special training? | No. Everyone can use Humasis COVID-19 Ag Test easily. But read instructions carefully before using. |
| 26 | Will new manufacturing processes need to be established or introduced? | Not Applicable |
| 27 | Is successful application of the medical device critically dependent on human factors such as the user interface? | Not Applicable |
| 27.1 | Are there any parts or component connected with medical device? | Not Applicable |

| | | |
|---|---|---|
| 27.2 | Does the medical device have a control Interface? | Not Applicable |
| 27.3 | Does the medical device display information? | Not Applicable |
| 27.4 | Is the medical device controlled by a menu? | Not Applicable |
| 28 | Is the medical device intended to be mobile or portable? | Not Applicable |
| 29 | Is there a definition of Intended Use and patient group, including user profile and conditions of use? | Yes, please refer to Instructions for information. |
| 30 | Are frequently used functions of the device defined? | Yes, please refer to Instructions for information. |
| 31 | Are there specifications for usability functions? | Not Applicable |
| 32 | Does the device require user interaction with respect to operation, maintenance, cleaning, or parts installation? | Not Applicable |
| 33 | Given the combination of user interface, user population, and operating conditions, are errors likely? | Not Applicable |
| 34 | Has a Usability / Design validation test plan been developed? | Not Applicable |
| 35 | Is someone integral to the design team focusing on the user-related issues? Are users involved? | Not Applicable |
| 36 | Has the design team checked the literature and historical data for useful human factors information? | Not Applicable |
| 37 | Has the project team done testing in simulated and/or actual use environments? | Not Applicable |
| 38 | Have user requirements been met? | Not Applicable |
| 39 | Has the outcome of the usability engineering and risk management process been considered in labelling? | Not Applicable |

## 5. Risk estimation

| Severity(five classifications) | Likelihood(Five classifications) |
|---|---|
| 1 = negligible(little or no potential of injury)<br>2 = minor(temporary injury or harm not requiring professional medical intervention)<br>3 = Serious(potential of injury or harm requiring professional medical intervention)<br>4 = critical( permanent impartment or life-threatening injury/ harm)<br>5 = catastrophic(potential of death) | 5 = frequent($>1^{-1}$)<br>4 = probable($1^{-1} \sim 10^{-1}$)<br>3 = occasional($10^{-2} \sim 10^{-4}$)<br>2 = remote($10^{-4} \sim 10^{-6}$)<br>1 = improbable($<10^{-6}$) |

Risk = Severity X Likelihood 1~4,6 (**ACC : Acceptable**)

5, 8~ 25 (**N/ACC : Not acceptable**)

**Severity**

| **Likelihood** | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| 5 | **N/ACC** | **N/ACC** | **N/ACC** | **N/ACC** | **N/ACC** |
| 4 | **ACC** | **N/ACC** | **N/ACC** | **N/ACC** | **N/ACC** |
| 3 | **ACC** | **ACC** | **N/ACC** | **N/ACC** | **N/ACC** |
| 2 | **ACC** | **ACC** | **ACC** | **N/ACC** | **N/ACC** |
| 1 | **ACC** | **ACC** | **ACC** | **ACC** | **N/ACC** |

## 6. Risk management plan

: Please refer to ANNEX. 1 / Document No. RN-20-004-D001

## 7. Risk management report

The risk analysis report comprises the analysis and action to potential risks of the COVID-19 Ag test by Humasis Co. Ltd. In accordance with EN ISO14971:2012 and EN 62366:2008 standard. The COVID-19 Ag test (Humasis COVID-19 Ag Test) conforms to the standard and can be applied safety to users.

: Please refer to ANNEX. 2 / Document No. RN-20-004-D002

## 8. Risk analysis report

: Please refer to ANNEX. 3 / Document No. RN-20-004-D003

## 9. Usability engineering

: Please refer to ANNEX. 4 / Document No. RN-20-004-D004

## 10. Risk/Benefit analysis

: As the results of risk analysis and reevaluation of residual risk, all risks were reduced or eliminated, and there was no risk for the risk/benefit analysis.

## 11. Post production information

The post-production information will be continuously collected and evaluated for potential influence to the risk of product, any of which will initiate the risk analysis process

- Process Monitoring (Humasis-P-7020)
- Feedback process (Humasis-P-8010)
- Recall process (Humasis-P-8071)