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IVD AND POCT PRODUCTS MANUFACTURER

Summary of the Risk Analysis

1. Members of Risk Analysis Team

Research and Development Department: Chen Huan, Cui Ranglian
Customer Service Department: Lin Jinchang
Product Registration & Testing Department: Zeng Xiangfu
Quality Control Department: Gan Xiaojing
Production Department: Zhang Hailong

2. Purpose and Characteristic of the Products

NO.	Questions	Answer
1	What is the intended use and how is the medical device to be used?	This kit is used for the qualitative detection of SARS-CoV-2 antigen in human oropharyngeal swabs and nasopharyngeal swab samples in vitro.
2	Is the medical device intended to be implanted?	No， it's a reagent , not implanted device.
3	Is the medical device intended to be in contract with the patient or other persons?	No，not contract with human.
4	What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	Quality materials, reagents and so on.
5	Is energy delivered to or extracted from the patient?	No
6	Are substances delivered to or extracted from the Patient?	No

7	Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	No
8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	No
9	Is the medical device intended to be routinely cleaned and disinfected by the user?	No
10	Is the medical device intended to modify the patient environment?	No
11	Are measurements taken?	No
12	Is the medical device interpretative?	No, it's a reagent, not a device.
13	Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	No
14	Are there unwanted outputs of energy and substances?	Yes, waste liquid produced after specimen analysis. So users should depose the waste conform to the local law.
15	Is the medical device susceptible to environmental influences?	Yes，operation，storage environment and so on. The reagent is to be used and stored at 2℃-30℃
16	Does the medical device influence the environment?	Yes, waste liquid etc. May not be washed directly into water source. Washed into the sewer system after diluted with large amounts of water.
17	Are there essential consumables or accessories associated with medical device?	No.
18	Is maintenance or calibration necessary?	No.
19	Does the medical device contain software?	No, it's a reagent, not a device.
20	Does the medical device have a restricted shelf-life?	Yes, The shelf –life of Concentrated cleanser is two year.
21	Are there any delayed or long-term use effects?	No
22	To what mechanical forces will the medical device be subjected?	No

23	What determines the lifetime of the medical device?	Yes. The temperature and time of shelf-life can make the performance go down. So the srip should be use within 1 hour after opening . To be used and stored at 2℃-30℃.
24	Is the medical device intended for single use?	Yes
25	Is safe decommissioning or disposal of the medical device necessary?	Yes. Dispose the waste with the local regulation.
26	Does installation or use of the medical device require special training or special skills?	Yes, users need the specialized training from persons designated by the manufacturers or learning from the user's manual.
27	How will information for safe use be provided?	It can be provided by the Persons designated by the manufacturers or agent for training and some information for safe will be given in the use manual and the label.
28	Will new manufacturing processes need to be established or introduced?	No
29	Is successful application of the medical device critically dependent on human factors such as the user interface?	Yes, up to whether operators correctly use the reagent.
29.1	Can the user interface design features contribute to use error?	No
29.2	Is the medical device used in an environment where distractions can cause use error?	No
29.3	Does the medical device have connecting parts or accessories?	No
29.4	Does the medical device have a control interface?	No
29.5	Does the medical device display information?	No
29.6	Is the medical device controlled by menu?	No
29.7	Will the medical device be used by persons with special needs?	Yes, users need the specialized training from persons designated by the manufacturers or learning from the user's manual.
29.8	Can the user interface be used to initiate user actions?	No

30	Does the medical device use an alarm system?	No
31	In what way(s) might the medical device be deliberately misused?	Yes, when the users neglect of manufacture's recommended maintenance.
32	Does the medical device hold data critical to patient care?	No
33	Is the medical device intended to be mobile or portable?	Yes, it is portable.
34	Does the use of the medical device depend on essential performance?	No

3. Standard of Risk Evaluation

Severity

Severity is classed four levels according to the possible damage:

1= negligible（maybe lead to slight damage or no damage)

2= minor（maybe lead to damage or harm)

3= Serious (injury or impairment reuiring professional medical intervention)

4= critical（maybe lead to death, serious damage or harm)

5= catastrophic（may be lead death of many people our serious damage)

Likelihood

Likelihood is classed 6 levels according to probability of occurrence in every year.

1= incredible ($<10^{-6}$)

2= unlikely (10^{-5}-10^{-6})

3= occasional (10^{-4}-10^{-5})

4= probable(10^{-3}-10^{-4})

5= frequent ($\geq10^{-3}$)

Risk= Severity×Likelihood

Result	Acceptability
1～5	Acceptable
6～9	Alarm, worry
10～25	Unacceptable

Signed: Xingchao Deng

DAY :2020/10/15

Stamp: