Risk Analysis Report

Identification of qualitative and quantitative characteristics (acc.to EN ISO 14971:2016,cl. 4.2)

Questions	Answer
C.2.1 What is the intended use and how is the medical device to be used?	The LYHER® Novel Corona virus (COVID-19) Antigen Te st Kit (Colloidal Gold Metho d) is an in vitro immunoass ay. The assay is for the dire ct and qualitative detection of SARS-CoV-2 nucleoprotei n antigens from nasopharyn geal secretions and orophar yngeal secretions specimen s. The kit is for in vitro diag nostic use.
C.2.2 Is the medical device intended to be implanted?	NO.
C.2.3 Is the medical device intended to be in contact with the patient or other persons?	Yes, The product not in contact with the surface of the body intact skin
C.2.4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	See Instruction for User
C.2.5 Is energy delivered to or extracted from the patient?	NO.
C.2.6 Are substances delivered to or extracted from the patient?	NO.
C.2.7 Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	NO.
C.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	YES.
C.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user?	NO.
C.2.10 Is the medical device intended to modify the patient environment?	NO.
C.2.11 Are measurements taken?	NO.
C.2.12 Is the medical device interpretative?	NO.
C.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	NO.
C.2.14 Are there unwanted outputs of energy or substances?	NO.
C.2.15 Is the medical device susceptible to environmental influences?	Yes.Store in a dry place at 2-30 ℃, protected from light.
C.2.16 Does the medical device influence the environment?	NO.
C.2.17 Are there essential consumables or accessories associated with the medical device?	NO.
C.2.18 Is maintenance or calibration necessary?	NO.
C.2.19 Does the medical device contain software?	NO.
C.2.20 Does the medical device have a restricted shelf-life?	18 months.
C.2.21 Are there any delayed or long-term use effects?	NO.
C.2.22 To what mechanical forces will the medical device be subjected?	NO.
C.2.23 What determines the lifetime of the medical device?	NO.

C.2.24 Is the medical device intended for single use?	YES, single use
C.2.25 Is safe decommissioning or disposal of the medical device necessary?	NO.
C.2.26 Does installation or use of the medical device require special training or special skills?	Yes.
C.2.27 How will information for safe use be provided?	Manual.
C.2.28 Will new manufacturing processes need to be established or introduced?	NO.
C.2.29 Is successful application of the medical device critically dependent on human factors such as the user interface? C.2.29.1 Can the user interface design features contribute to use error?	NO.
C.2.29.2 Is the medical device used in an environment where distractions can cause use error?	NO.
C.2.29.3 Does the medical device have connecting parts or accessories?	NO.
C.2.29.4 Does the medical device have a control interface?	NO.
C.2.29.5 Does the medical device display information?	NO.
C.2.29.6 Is the medical device controlled by a menu?	NO.
C.2.29.7 Will the medical device be used by persons with special needs?	NO.
C.2.29.8 Can the user interface be used to initiate user actions?	NO.
C.2.30 Does the medical device use an alarm system?	NO.
C.2.31 In what way(s) might the medical device be deliberately misused?	NO.
C.2.32 Does the medical device hold data critical to patient care?	NO.
C.2.33 Is the medical device intended to be mobile or portable?	YES. portable
C.2.34 Does the use of the medical device depend on essential performance?	NO.
Letters in the first column refer to EN ISO 14971:2012, cl. 4.2	

No	Hazard General	Identify hazards	Risk Evaluation S	O	D	RL	Risk Reduction Measure	Evidence	NH	ALOR
D2.	**Energy Hazards**									
1	Electricity	N/A								
2	Heat	N/A								
3	Mechanical force	N/A								
4	Ionizing radiation	N/A								
5	Non Ionizing radiation	N/A								
6	Electromagnetic fields									
7	Moving parts	N/A								
8	Suspended masses	N/A								
9	Patient support device failure	N/A								
10	Pressure(vessel rupture)	N/A								
11	Acoustic pressure	N/A								
12	Vibration	N/A								
13	Magnetic fields(e.g. MRI)	N/A								
D3.	**Biological hazards**									
1	Bio-contamination	The product may be contaminated if the package is damaged.	2	3	1	6	Single use and package control	Instruction		Acc
2	Bio-incompatibility	The product may cause the user uncomfortable if the material is not OK	2	4	1	8	Choose raw materials of fabrics with qualified biological properties	See test report		Acc
3	Incorrect formulation(chemical composition)	The product may cause the user uncomfortable if the material is not OK	2	3	1	6	Choose safe chemical raw material in recognize to ensure that the ingredients are accurate.	See test report		Acc

No	Hazard General	Identify hazards	Risk Evaluation S	O	D	RL	Risk Reduction Measure	Evidence	NH	ALOR
4	Toxicity	The product may cause the user uncomfortable if the material is not OK	2	4	1	8	Choose raw materials of fabrics with cyto toxicity meeting the requirements	See test report		Acc
5	Allergenicity	N/A								
6	Mutagenicity	N/A								
7	Oncogenicity	N/A								
8	Teratogenicity	N/A								
9	Carcinogenicity	N/A								
10	Re-and/or cross-infection	The product is single use product and could not be re used.	2	3	2	12	Ensure that the products are for single use shall be shown on the instruction of use and labels.	Instruction of use and Labels		Acc
11	Pyrogenicity	The product may cause the user uncomfortable if the material is not OK	2	3	1	6	Ensure that microb content in the production environment meets the requirements.	Products operating instructions		Acc
12	Inability to maintain hygienic safety	The product may cause the user uncomfortable if the material is not OK	2	3	2	12	Ensure that microb content in the production environment meets the requirements.	Products operating instructions		Acc
13	Degradation	N/A								

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D4.	**Environmental hazards and contributory factors**									
1.	Electromagnetic fields	N/A								
2.	Inadequate supply of power or coolant	N/A								
3.	Susceptibility to electromagnetic interference	N/A								
4.	Emissions of electromagnetic interference	N/A								
5.	Inadequate supply of power or coolant	N/A								
6.	Inadequate supply of coolant	N/A								
7.	Storage or operation outside prescribed environmental conditions	N/A								
8.	Incompatibility with other devices	N/A								
9.	Accidental mechanical damage	N/A								
10.	Contamination due to waste products and /or device disposal	N/A								

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D5. Hazards resulting from incorrect output of energy and substances										
1.	Electricity	NA								
2.	Radiation	NA								
3.	Volume	NA								
4.	Pressure	NA								
5.	supply of medical gases	NA								
6.	supply of anaesthetic agents	NA								
D6. Hazards related to the use of the device and contributory factors										
1	Inadequate labeling	The inadequate labeling may cause misuse	2	2	1	4	Strengthen amending the label for warning	Refer to label		Acc
2	Inadequate operating instructions	The inadequate operating instructions may cause misuse	2	2	1	4	Strengthen amending the operating instructions	See instruction of use		Acc
2.1	Inadequate specification of accessories	NA								
2.2	Inadequate specification of pre-use checks	The device may be damaged	2	2	1	4	To strengthen pre-use checks	See instruction of use		Acc
2.3	Over-complicated operating instructions	NA								
2.4	Inadequate specification of service and maintenance	NA								
3	Use by unskilled/untrained personnel	The device may be damaged	2	3	1	6	To strengthen training	See instruction of use		Acc

No	Hazard	Identify hazards	Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General		S	O	D	RL				
4	Reasonably foreseeable misuse	NA								
5	Insufficient warning of side effects	The device has no side effects								
6	Inadequate warning of hazards likely with re-use of single use devices	NA								
7	Incorrect measurement and other metrological aspects	NA								
8	Incompatibility with consumables/accessories/other devices	NA								
9	Sharp side	NA								
D7. Complicated operation										
1	Mistakes and judgement errors	NA								
2	Lapses and cognitive recall errors	NA								
3	Slips and blunders (mental or physical)	NA								

No	Hazard	Identify hazards	Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General		S	O	D	RL				
4	Violation or abbreviation of instructions, procedures, etc.,	NA								
5	Complex or confusing control system	NA								
6	Ambiguous or unclear device state	NA								
7	0Ambiguous or unclear presentation of settings, measurements or other information	NA								
8	Mispresentation of results	NA								
9	Insufficient visibility, audibility or tactility	NA								
10	Poor mapping of controls to action, or of displayed information to actual state	NA								
11	Controversial modes or mappings as compared to existing equipment	NA								

No	Hazard General	Identify hazards	Risk Evaluation S	O	D	RL	Risk Reduction Measure	Evidence	NH	ALOR
D8. Hazards arising from functional failure, maintenance and ageing										
1	Erroneous data transfer	NA								
2	Lack of , or inadequate specification for maintenance including inadequate specification of post maintenance functional checks	The device may not work well if lack of inadequate post maintenance or functional checks	2	1	3	6	Strengthen post maintenance and functional checks	See instruction of use		ACC
3	Inadequate maintenance	The lifetime of the device may be reduced	1	2	2	4	Strengthen management	See instruction of use		ACC
4	Lack of adequate determination of end of device life	NA								
5	Loss of mechanical integrity	NA								
6	Inadequate packaging(contaminatio n and /or deterioration of the device)	The lifetime of the device may be reduced	3	2	1	6				Acc
7	Re-use and / or Improper re-use	NA								
8	Deterioration in function (e.g. gradual occlusion of fluid/gas path, or change in resistance to flow, electrical conductivity) as a result of repeated use.	NA								

B2. Additional hazards to in vitro diagnostic medical devices										
1	Batch inhomogeneity, batch-to-batch inconsistency	Leading to product traceability or customer complaints	4	2	1	8	Strengthen batch management and supervision	See Lot number management regulations		ACC
2	Common interfering factors	Affect product quality and reduce product functions	3	2	1	6	Control and strengthen the control of interference factors	See instruction of use		ACC
3	Carry-over effects	NA								
4	Specimen identification errors	Lead to misuse and customer complaints	3	2	1	6	Strengthen product identification control	See instruction of use		ACC
5	Stability problems (in storage, in shipping, in use, after first opening of the container)	Affect product quality and reduce product functions	2	2	2	8	Strengthen product quality inspection and transportation control	See Design and development program files		ACC
6	Problems related to taking, preparation and stability of speciments	Reduce the functional effect of the product	3	2	2	12	Increase product quality inspection and product stability analysis control	See stability study report		ACC
7	Inadequate specification of prerequisites	Lead to misuse	3	2	2	12	Complete product manual	See instruction of use		ACC
8	Inadequate test characteristics	Lead to product quality substandard	4	2	2	16	Strengthen product quality control and arrange products for full inspection	See test report		ACC

Abbreviations used

RE	Risk Evaluation
S	Severity (9 –very severe, 0 –not severe)
O	Occurrence (9 –often, 0 –never)
D	Detection (9 –impossible to detect before risk occurs, 0 –will be certainly detected before risk occurs)
RL	Risk Level = Severity × Occurrence × Detection 1-9: Neglectable risk, no further actions; 9-24: Moderate: minimal risk, preventive action recommended; 25-48: Moderate risk, preventive action required; >48: Risk is usually not acceptable
RRM	Risk Reduction Measure
NH	New hazard generated (no/ yes - if yes, then number of new hazard indicated)
ALOR	Acceptable Level of Risk

Conclusion:

According to the analysis of the risk, all the risk has been identified and the risks which are none accepted have been controlled by measure taken by the manufacturer. In one word, the risk has been managed accordingly.

The above products are analyzed according to EN ISO14971: 2012. The analysis is objective and the conclusion is valid. Through security risk control, the risk level of the product is reduced, and all items are within acceptable ranges. In summary, all risks of the product have been reduced to acceptable levels through risk control measures, and no additional risks have been generated during the period. The benefits of the product outweigh the risks, so it can be seen that using the product is safe and reliable. Through prior security risk analysis and preventive measures, we have reduced hazards to acceptable levels throughout the development phase. After the product reaches the user, precautionary measures such as the user's qualification will be notified with warning statements in the instruction manual to minimize harm. The product will be continuously improved from user feedback in future use to minimize risks.