World Health Organization

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Prequalification Unit Inspection services
WHO DESK ASSESSMENT REPORT
Emergency Use Listing (EUL)
Review of Quality Management System Documentation

Part 1	**General information**
Company information	
Name of manufacturer	Joysbio (Tianjin) Biotechnology Co., Ltd
Corporate address of manufacturer	Tianjin International Joint Academy Biotechnology & Medicine 9th Floor, No. 220, Dongting Road, TEDA 300457 Tianjin, China
Contact person	Ms Yang Man Director Registration Department Email: molly@joysbio.com Tel: _+86-13821759311
Manufacturing site(s) under assessment	
Address of manufacturing site if different from that given above	Same as above
Desk assessment details	
Date of review	18-23 November 2020
EUL number(s)	EUL 0582-223-00
Inspector(s)	Conrad Mark
Products covered by this desk assessment	SARSV-2 Antigen Rapid Test Kit (Colloidal Gold)
List of documents submitted	WHO-EUL Quality System Information 312 pages
Any documents missing?	

Abbreviations	**Meaning**
NC	Non-conformity
QC	Quality control
QMS	Quality management system

Part 2	**Summary of the assessment of supporting documentation**

1. Certification and audit reports:

ISO 13485:2016 certificate number SX 60143180 0001 was provided.

Organization:F

JOYSBIO (Tianjin) Biotechnology CO., Ltd.

Tianjin International Joint Academy of Biotechnology & Medicine 9th Floor No. 220, Dongting Road, TEDA 300457 Tianjin P.R China

Issued by:
TUV Rheinland LGA Products GmbH

Validity:
Effective: 2020-06-07 Expiry: 2022-10-12

Scope: Design and Development, Manufactu
In Vitro Diagnostic Test Kits use
Cancer, Cardiac Markers, Fertilit
Testing Drugs of Abuse Sexually

A surveillance audit report dated 2020-01-16 was submitted. The audit was conducted by TUV Rheinland. Areas audited included: customer satisfaction/customer feedback, design and development, production and service provision and warehouse, identification of processes, documentation requirements, resource management, purchasing, internal audit, quality management system, monitoring and measurement of products, control of nonconforming products, improvement, corrective and preventive actions etc.

2. Quality Manual:

The quality manual (QM-001) version 2.0 was submitted. The Quality manual described the company's policies, procedures and processes. The quality manual was based on the following standards YY/T 0287-2017 idt ISO13485:2016, EN ISO 13485:2016, requirements of Medical Device Quality Management System for regulations, Medical device Production Quality Management Specifications Appendix in-vitro Diagnostic Reagents and IVDD 98/79EC Instructions for Medical Devices for in-vitro diagnostics.

The following clauses of the ISO 13485 were not applicable (Page 10 and 11 of the Quality Manual):

ISO 13485 Clause	Justification
Clause 7.5.3 Installation activities	Our products do not require on-site installation
Clause 7.5.4 Service activities	Our products are invitro diagnostics reagents and do not involve maintenance, regular maintenance and service activities
Clause 7.55 Special requirements for Sterile Medical Devices	Our products do not belong to sterile devices
Clause 7.5.7 Requirements for validation of processes for sterilization and sterile barrier systems	Our products do not belong to sterile devices
Clause 7.5.9.2 Requirements for implantable medical	Our products do not belong to implantable medical devices

devices	

Quality policy and objectives (Refer to Quality Manual page 26, 68 and Surveillance audit report page 7)
The quality policy and quality objectives were stated in the quality manual. Quality objectives were approved by the General Manager. The audit report indicates that the company implemented and maintained procedures and processes to achieve defined quality objectives.

Control of documents (Refer to Quality Manual page 22 and Surveillance audit report page 7)
The company's quality management system documents were categorised into four levels namely: Quality Manual, Program files, Production documents/External documents and record templates. Reference is made to the Document control program (QP-02) and Control of Records Program (QP-03). The procedures defined controls needed for the identification, review, approval, distribution, and control of quality management system documents. The quality management department is responsible for centralized management of QMS documents. The retention period for records was defined. From the audit report; document and record control were implemented effectively.

Responsibility, Authority and Communication (Refer to Quality Manual page 17, 25, 50, 69 and Surveillance audit report page 8)
Reference is made to the Management Responsibility Program (QP-04). The organization chart was provided. The Management Representative reported to the General Manager. responsibilities of the Management representative and General Manager were outlined in Quality Manual.
The management representative was responsible for the establishment, implementation and maintenance of the quality management system.

Purchasing (Refer to Surveillance audit report page 9 and Quality Manual page 46)
Reference is made to the Purchasing Control Program (QP-16). Purchased goods are classified into 3 categories A, B and C. The organization established criteria for evaluation and selection of suppliers. Records were maintained. From the audit report, the purchasing process was found to conform with the ISO 13485:2016 requirements.

Internal audits (refer to the Quality Manual page 56 and Surveillance audit report page 11)
Reference is made to the Internal audit procedure (QP-26). The planning, preparation, implementation, and review of the audit report were described. Review of the audit report indicated that Internal audits were conducted in conformity with the requirements of the ISO 13485:2016 standard. The internal audit process allowed for verification of actions undertaken.

Customer satisfaction/Customer feedback/Complaint handling (Refer to Quality Manual page 54 and Audit report page 11)
The Customer complaint feedback handling control procedure (QP-24) was provided. The procedure provided for root cause investigation, implementation of CAPA and maintenance of records. Customer complaint investigation reports are prepared by the General Manager.
In the quality manual; reference is also made to the Feedback process control program (QP-23). From the audit report; the vigilance system procedure (in accordance with MEDDEV 2.12/1) was in place.

(4) If the complaint investigation finds that the activitie
the organization lead to non-conformities, such as suppl
and logistics that provide product transportation services,

Reporting of Incidents and recalls (Refer to the Quality Manual page 56)
The procedure for Adverse event monitoring report control (QP-25) and the procedure for recall (QP-30) were provided. The different classes of recall and timelines for reporting of adverse events in China timelines were defined. The Quality management department is responsible for the analysis and evaluation of adverse events. A post-marketing surveillance plan was also provided.
The manufacturer provided a commitment to follow the WHO requirements for Post Market Surveillance for in-vitro diagnostics.

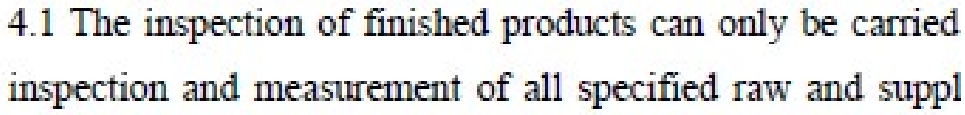
If our company's SARS-CoV-2 Antigen Rapid Test Kit
enters the WHO emergency use list, In the process of use, t
"Guiding Opinions of the World Health Organization or
Diagnostic Reagent Monitoring", adopt continuous monitc
safety, quality, performance, etc., and continuously disc
possible risks. And take measures to control and redu

Identification and traceability (Quality Manual page 50, 51 and Surveillance audit report page 10)
Reference is made to the Product identification Program (QP-19) and Traceability control program (QP-20). The identification of products is maintained throughout the purchasing, production, storage and service processes.

(3) Intermediate materials, semi-finished products anc
production process are identified by material number, ba
(2) When products need tracing, tracing shall be carried

Corrective Action and Preventive Action (Refer to Quality Manual section 8.5.3 and Surveillance audit report Page 12)
The procedure for Corrective and preventive Measures (QP-31) was provided. The procedure provided for determination of the cause of the nonconformity and verification of the corrective actions to ensure that they have no adverse effect on the ability to meet applicable regulatory requirements or performance of the medical device. Records were maintained.

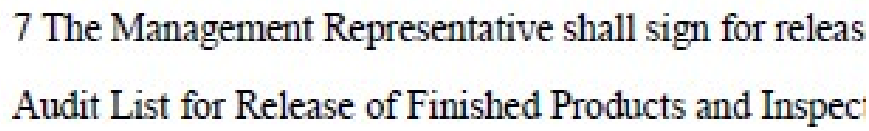
Monitoring and Measurement of products (Quality Manual Page 43and surveillance audit report page 12)
The procedure for Product Monitoring and Measurement (QP-27) was provided. The procedure described the monitoring and inspection at different stages of product realization.


4.1 The inspection of finished products can only be carried
inspection and measurement of all specified raw and suppl

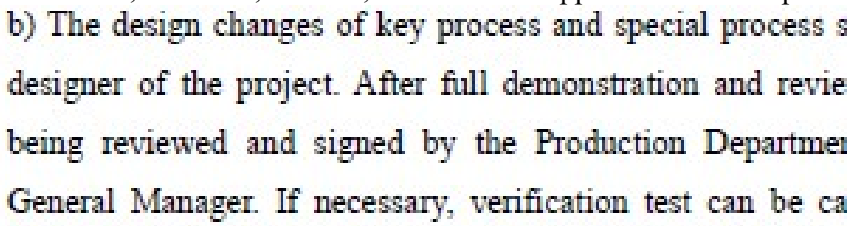
3. List of current quality management documentation:
List of current quality management documentation provided.

4. Standard operating procedures for:

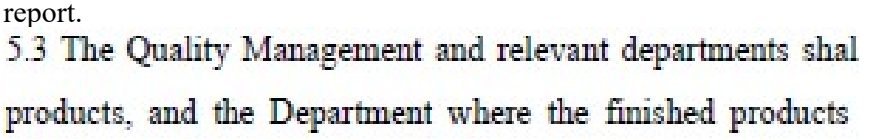
i) **Quality control (QC) and batch release procedures:**
The procedures for Product Monitoring and Measurement (QP-27) and Product Release (SOP-QA-001) were provided. The quality controls measures (including inspection) for the raw materials, packaging materials, semi-finished products and finished products were described.


7 The Management Representative shall sign for releas
Audit List for Release of Finished Products and Inspec

ii) **Control of design and development change procedures:**
The procedures for Design and development (QP-12), Changes of design and development (QP-15) and Management of Change control procedure (SMP-WJ-008) were provided. The technical department is responsible for preparation of a risk analysis report. Changes in design and development were identified and documented, reviewed, verified, validated and approved before implementation.


b) The design changes of key process and special process s
designer of the project. After full demonstration and revie
being reviewed and signed by the Production Departmer
General Manager. If necessary, verification test can be ca

iii) Control of nonconforming goods/processes:
The procedures for Control of Non-conforming Products (QP-28), Deviation System (SMP-QA-006) and Investigation and Handling of excessive results (SOP-QC-018) were provided. The quality management department is responsible for the classification of deviations and approval of the deviation investigation report.


5.3 The Quality Management and relevant departments shal
products, and the Department where the finished products

iv) Management Review:
Minutes of the Management Review held on 30th December 2019 were provided. Management review was performed in accordance with the requirements of the ISO 13485:2016 standard.

5. Manufacturing flowchart including in-process control points:

Process procedures for the manufacture of SARS-CoV-2 Antigen Test Kit (Colloidal Gold) STP-0-032 was provided. The manufacturing flow chart was also provided. A description of the manufacturing process was also provided. A manufacturing process flow chart was also provided. Some of the key/special manufacturing processes included preparation of colloidal gold particles, coating and drying of colloidal gold particles, carding, packaging ad labelling. In-process control points were indicated.

6. List of critical suppliers:

List of critical suppliers was provided.

7. General information about the product:

i) When was it first placed on the market:

The project was initaited on 2nd January 2020.

4. Date of product launch: April 6, 2020

ii) Details of the distributors experience with the product (including research-use-only products), especially (but not limited to) number of products distributed, number of customer complaints (if any), type(s) of complaint(s) and customer feedback:

The product has been distributed to Morocco, Mexico and several European countries including Spain, Netherlands, Denmark, Italy, Sweden etc. The list of countries and quantities of the product distributed was provided. No customer complaints have yet been received. Evidence of registration with CIBG, Ministry of Health, wellbeing and Sports, Netherlands (Letter dated 12th May 2020) provided. A declaration of conformity was also provided. Lotus NL B.V is indicated as the European Representative.

iii) Details of the manufacturing output and capacity:

Production capacity: With the area of 2000 square meters, there are

operators, 5 production lines with Advanced production equipment

days, the current output of 300,000 test kit / day; and the current i

8. Summary:

The manufacturer's QMS was designed to meet the requirements of ISO 13485:2016. The documentation structure, procedures and process interactions were described in the quality manual. Management documented its commitment to implement and maintain an effective quality management system. A copy of the ISO 13485: 2016 surveillance audit report by TUV Rheinland was provided. Key quality management procedures were reviewed. A commitment to follow WHO procedures on post-market surveillance of invitro diagnostics was provided. The process for the manufacture of SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) was described. Evidence of registration with CIBG, Ministry of Health, wellbeing and Sports, Netherlands and declaration of conformity were also provided.

Part 3	**Conclusion - Desk assessment outcome**

Based on the on the QMS evidence received and reviewed, it is considered that a desk assessment is acceptable. The site ***Joysbio (Tianjin) Biotechnology Co., Ltd***, located at ***Tianjin International Joint Academy Biotechnology & Medicine 9th Floor, No. 220, Dongting Road, TEDA 300457 Tianjin, China***, does fulfil all the requirements described in the "*Instructions and requirements for Emergency Use Listing (EUL) submission: In vitro diagnostics detecting SARS-CoV-2 nucleic acid and rapid diagnostics tests detecting SARS-CoV-2 antigens* (PQDx_ 347 version 4; 09 June 2020)".

Name	Conrad Mark
Signature	
Approval Date	23 November 2020

Part 4	**References**

1. Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid (PQDx_347). (https://www.who.int/diagnostics_laboratory/200228_final_pqt_ivd_347_instruction_ncov_nat_eul.pdf?ua=1)

2. ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

3. ISO 9001:2015 Quality management systems - Requirements

4. Medical devices - Application of risk management to medical devices - ISO14971:2007

5. GHTF/SG3/N19:2012 "Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange"

6. GHTF/SG4/(99)28 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements

7. GHTF/SG4/N30R20:2006 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategy

8. GHTF/SG4(pd1)/N33R16:2007 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 3: Regulatory Audit Reports