Vigilance System

Product Name: COVID-19 Antigen Rapid Test (Colloidal Gold)

Company Name: Joinstar Biomedical Technology Co.,Ltd.

Prepared By/Date: 5.1.2e /30/11/2020

Reviewed By/ Date: 5.1.2e /30/11/2020

Approved By/ Date: 5.1.2e /30/11/2020

1 Purpose

The purpose of the document is to improve the protection of health and safety of patients, users and others by reducing the likelihood of the same type adverse incident being repeated in different places at different times. It will also ensure that any incidents falling within the criteria for reporting will be identified and passed on to the Competent Authority within the stipulated times.

2 Scope

2.1 The document refers to incidents occurring within the Members States of European Community and all other States within the European Economic Area (EEA) with regard to:

A.Medical devices that carry the CE mark.

B.Medical devices that do not carry the CE mark, where such incidents lead to corrective action relevant to CE marked medical devices.

2.2 If incidents that occur outside the EEA lead to corrective action relevant to CE marked medical devices that are offered for sale or are used within the EEA,then our company should notify the relevant Competent Auithorities.

3 Responsibility

3.1 To notify the Competent Authority regarding incidents falling within the criteria for reporting in conjunction with the European Representative.

3.2 To ensure that incidents coming to the attention of any part of the company,including EC representative, distributors, servicemen, or service agents, will be rapidly transmitted to TQC office of the company where they will be analyzed for their significance.

4 Document description

4.1 Decision Process

TQC office will examine all complaints or information about incidents, the following points should be assessed when deciding whether an incident should be reported to Competent Authority.

A.The type of incident

B.Whether any medical device may have been involve which was made by our company.

C.Whether the incident was caused (wholly or partly), or could have been caused,by the device or by shortcoming in the information supplied with the device.

4.2 The types of incidents to be reported

In assessing the type of incident, TQC office should consult with the medical practitioner involved or other health-care professional under the help of EC representative or distributors.

The following incidents defined in the Directives should be reported:

4.2.1 Those which led to death

Those which led to a serious deterioration in state of health of a patient, user or other person, which include:

A.Life threatening illness or injury.

B.Permanent impairment of a body function or permanent damage to a body structure.

C.A condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

4.2.2 Those which might have led to death or serious deterioration in health, such potential incidents are to be known as near incidents.

4.3 The information included which should be reported.

In assessing the link between the medical device and the incident, the following information should be considered:

A.The opinion & based on available evidence of health care professionals.

B.The results of the manufacture's own preliminary assessment of the incident.

C.Evidence of previous, similar incidents.

D.Other evidence hold by the manufacturer.

The following information that may be associated with an incident which should be reported with an incident that should be reported.

4.3.1 Malfunction or deterioration in the characteristics and / or performance of a device.

4.3.2 A device that shows no malfunction or deterioration, but nevertheless has a characteristic that could lead to an incident should be reported as a near incident.

4.3.3 Inaccuracy in the instruction leaflet, or directions for use may include omissions and deficiencies.

4.4 Time scale for the initial reporting of an incident or near incident TQC office should make initial report and submit to the Competent Authority via EC representative within the following times:

1)incidents: 10 days.

2)near incidents: 30 days.

4.5 Systematic recalls

4.5.1 The decision for the systematic recall of a device due to any technical or medical reason should be notified by the manufacturer to a Competent Authority via our EC representative.

4.5.2 TQC office should provide the concrete materials to general manager, who will make final decision on the issuing of advisory notices and product recalls.

4.5.3 Copies of advisory notices should be sent to the Competent Authorities of the countries to which they are applicable.

4.6 The Competent Authority should be reported.TQC will submit the initial report according to the following via EC representative.

4.6.1 In general, the report should be to the Competent Authority.

4.6.2 Reports on incidents concerning devices in class IIa occurring in countries outside the EEA and which result in corrective action, should be made to the Competent Authority in the State where the Notified Body is situated.

4.7 Details to be included in initial report

The content of the initial report made by the manufacturer to the Competent Authority is given (as per attachment).

4.8 Procedure followed the initial report

4.8.1 TQC office with EC representative together normally performs the investigation following the initial report, and keeps the Competent Authority informed of progress at an appropriate.

4.8.2 If the manufacture is not able to perform the investigation of an incident, then be should inform the Competent Authority without delay.

4.9 Outcome of an investigation and follow-up

4.9.1 Normally, the manufacturer should take the action necessary following the investigation, including consultation with Competent Authority and performing any recalls.

4.9.2 TQC office should make final report that is a written statement of outcome of the investigation and of any action, under the help of EC representative, and submit to the Competent Authority by EC representative.

4.9.3 The content of final report is given (as per attachment).

4.9.4 Outcome may include, for example:

1)no action.

2)additional surveillance or follow-- up of devices in use.

3)dissemination of information to users, e.g. by advisory notice.

4)corrective action on future product.

5)corrective action on devices in use.

6)recall.

5 Biliography

5.1 EC—Directive 98/79/EC

5.2 Guidelines on a medical devices vigilance system MDEV_2.12-1_REV.8_January_20

6 Appendices

6.1 List of Competent Authority for Vigilance System.
6.2 Suggested incident report format (initial report and final report)
6.3 Simplified flow chart illustrating the reporting of recall

Technical Files (Part A)	File Number: CE-01
	Revision: A/0
Control Procedure of Vigilance System	Chapter: 13
	Page Code: 4 of 7

List of Competent Authority for Vigilance System

COUNTIRIES/NMES	COMPANIES	ADDRESSES	PHONE	FAX
AUSTRIS Dr 5.1.2e	Federal Ministry of Labour,Health And Social Affairs	Stubenring,1 A 1010 Vienna	5.1.2e	43/1/715.73.12
BELGIUM 5.1.2e	The ministry of Health, Pharmaceutical Inspectorate Medical Device Vigilance	Vesalius Building-Rijksadministratief Brussels	5.1.2e	32/2/210.4800
DENMARK 5.1.2e	The National Board of Health Medicines Division (5.1.2e @dkma.dk)	Fredeerikssundsej 378 DK-2700 Bronshoj	45/44/889.111 45/44/889.265 (direct line)	45/44/839.195
FINLAND 5.1.2e	Medical Devices Centre Natinal Agency for Medical	Mannerheimintie166-po BOX 55 FIN-00301 Helsinki	5.1.2e	35/9/4733-4266
FRANCE Mr. 5.1.2e	Ministere de la sante; Direction des Hopitaux(site materiovigilance:http/www.sante gouv.fr)	1 Place Fontenoy F-75350 paris 07SP	5.1.2e	33/1/40/564963
GERMANY 5.1.2e	Bundesinstitut fur Arzneimittel und Medizin-produkte; Geschaftsstelle Medizinprodukte	Seestr.10-11D-13353 Berlin	5.1.2e	49/30/786353065
GREECE Mr 5.1.2e	Ministry of Health,welfare and Social Services Biomedical Technology Department	17Aristoteleleous Street GR-101-87 Athes	5.1.2e	30/1/5223246
IRELAND Mr 5.1.2e	Department of Health	Hawkins House; IRL-Dublin 2	5.1.2e	353/1/6711947
ICELAND Mrs 5.1.2e	Ministry of Health and Social Service	Lantavegur 116 Is-150 Reykjavik	5.1.2e	35/45/519165
ITALY 5.1.2e	Ministry of Health,Department 11	p.le Industria 20; 1-00144 ROMA	5.1.2e	39/6/59942111
LUXEMBOURG Dr. 5.1.2e	Division de la Medcine Curative	4 rue Auguste Lumiere L-1950 Luxembourg	5.1.2e	352/480324
NETHERLAND 5.1.2e	Staatstoezicht op de Volksgezondheid,Inspectie Voor de Gezondheidszorg	Po Box 5850NL-2280 HW Rijswijk	5.1.2e	31/70/3407159
NORWAY Mrs 5.1.2e	National Board Health (Emil:ingeborg 5.1.2e 5.1.2e @helsetilsynet.dep telemax.no)(website:http://www.helsetilsynet.no)	Po box 8128 Dep N-0032 Oslo	5.1.2e	47/22/249017
PORTUGAL Non-active Evices:Mrs. 5.1.2e a) Active devices:Mr 5.1.2e	INFARMED INSA	Parque Saude de Lisboa; Av.Do Brasil,53p-1700 Lisboa Codex Av Padre Cruz P-1699 Lisboa Codex	5.1.2e 5.1.2e	351/1/7959116 351/1/7573671
SPAIN Carmen 5.1.2e	Minidteril de sanidady Consumo Direccion General de Farmacia y products sanitarios	Paseo del prado 18/20 E-28071 Medrid	5.1.2e	34/1/5964400
SWEDEN 5.1.2e	National Board of Health and Welfare,Medical Devices	S-106 30 stockholm	5.1.2e	46/8/7833294
SWITZERKAND Dr 5.1.2e	Office federal de la Sante publique	CH-3003 Bern	5.1.2e	41/31/3227646
UNITED KINGOOD 5.1.2e	Adverse Incident Center,Department of Health,Room	Hnnibal House,Elephant and Castle; UK-London SE16TQ	5.1.2e	44/171/9728109
COMMISSION CONTACT 5.1.2e	DG III.D.2(Medical devices sector,SC153/133)	200,rue de la Loi,B-1049 Brussels	5.1.2e (Secretarial)	32/2/2967013

INITIAL INCIDENT REPORT FORMAT

1. Administration

Add.: _____

_____

INITIAL INCIDENT

REPORT FORMAT

1. Administration
Add.: _____

2. Company profile:
a) company Authorization representative within EEA
b) Add.
c) Contact person
d) Telephone
e) Fax
f) Report date

3.(
A)
B)product type
C)model、specification
D)batch number
E)annex
F)certification number
G)Whether similar accident has occurred before? Have any impact on current report?
If yes, country reported, number of accident report
accident reporter:
Add.:
Telephone:
Report date:
h)date of accident:
I)accident content:
J)result (death or health damage, etc)
K)company preliminary comment
L)current position of product (if knows)
M)Intended date for following up report
N)corrective measures
O)plan for arranging time

FINAL REPORT FORMAT

1. Administration

Add.：_____

	Technical Files (Part A)	File Number: CE-01
		Revision: A/0
		7

2． company profile：
A)company Authorized representative within EEA
B)Add.
C)Contact person
D)Telephone
E)Fax
F)Date of report

3.Company name：

a） product name

b） product type

c） model、specification

d） batch code

e） annex

f） certification number

G)Whether similar accident has occurred before? Have any impact on current report?

Accident reporter：

Add.：

Telephone：

date of report：

H)Impact of other similar accident in company on current report

I)country reported, serial number of accident report

K)countries where products have been sold within EEA

L)date of commencing reporting

M)company investigation result

N)further investigation：

O)corrective measure：

P)plan for arranging time: