Vigilance System

according to MEDDEV 2.12/1 RAV8

Device: SARS-CoV-2 IgG/IgM Rapid Test

Manufacturer: Zhuhai Encode Medical Engineering Co., Ltd

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1. Purpose:

Through timely reporting and evaluation of accidents and release of relevant information, to reduce the recurrence of similar accidents, and to protect the safety and health of patients or users.

2. Range:

2.1 This procedure specifies the duties, working procedures, content and requirements of the control of the security system.

2.2 This procedure applies to the company's CE marked products.

2.3 This procedure is also applicable to accidents that occur with products bearing the CE mark in countries outside the European Union.

3 Definitions:

No

4 Duties:

4.1 Responsibilities of the company: After receiving the notification of the accident, conduct an investigation to determine the relationship between the responsible department and the EU authorized representative and the competent authority.

4.2 Responsibilities of the authorized representative of the European Union: Upon receipt of the accident information, the company shall be notified in a timely manner and assisted in handling it, and at the same time submit the initial report, follow-up report and final report to the competent authority of the European country.

4.3 Responsibilities of the seller: timely communicate customer complaints and accident reports to the company, and be responsible for maintaining product sales records.

5 Content：

5.1 The quality control department is responsible for analyzing the information of the accident report. After investigating with the R & D center and production department, and after confirming by the person in charge of quality, it is determined that it needs to report to the competent authority.

5.2 The company will report to the competent authority when the following three conditions are met:

5.2.1 An accident occurs;

5.2.2 The company's products may be one of the causes of the accident;

5.2.3 The accident will cause or may lead to the following situations:

5.2.3.1 Death of patient, user or other person

5.2.3.2 Patients, users or other persons suffer severe health damage.

5.3 When assessing the relationship between our products and accidents, we should consider:

5.3.1 The opinion of the doctor or expert (based on the evidence obtained);

5.3.2 evidence of previous similar accidents;

5.3.3 The company's preliminary assessment of the accident;

5.3.4 Other information and evidence held by the company.

5.4 The information in the accident report may include the following:

5.4.1 Failure or deterioration of device performance and / or characteristics.

5.4.2 There is no malfunction or deterioration of the device, but a certain characteristic may cause an accident, a "quasi-accident" report should be made.

5.4.3 The instruction manual of the device is not accurate enough, or is missing or insufficient.

5.5 Time Limits for Incident Reporting

After receiving the notification of the accident, the company shall be organized by the person in charge of quality. After completing the preliminary assessment report, the company shall notify the competent authority within the following specified time:

Serious but public accident: 2 days;

Death or unexpected accident: 10 days.

Other accidents: 30 days.

5.6 Reportable Medical Device Authority

5.6.1 If it occurs in an EU country, it should be reported to the competent authority of the country where the device accident occurred.

5.6.2 If it occurs in a country other than the European Union, it shall report to the competent authority of the country where the notified body is located.

5.6.3 When necessary, under the alert system, the company shall notify the authorized representatives of the EU and other agency representatives to report the accident.

5.6.4 The company should also report to the notified body that certifies it.

5.7 Safety Corrective Actions

Safety corrective actions are actions taken by the company to reduce the risk of death or serious health damage caused by the product, and generally include:

a) product changes;

b) product exchange;

c) product destruction or recycling;

d) The buyer refurbishes according to the company's change or new design

e) The company gives guidance on use

f) Technical or medical reasons for the recall of the product shall be notified to the competent authority.

For the recall of products caused by the above reasons, a "Safety Corrective Action Report" should be issued and sent to the competent authority of the relevant country.

5.8 Initial report

After receiving complaints and other accident information reports from customers of the competent authority, the company should have an initial report. For details of the initial report, please refer to the "accident report form".

5.9 Investigation after initial report

Based on the initial report, the company investigates the accident and timely reports the progress to authoritative organizations.

If the company is unable to investigate the accident, it should immediately notify the competent authority.

5.10 Investigation Follow-up and Conclusion

5.10.1 Under normal circumstances, the Company shall take appropriate measures based on the results of the investigation after the investigation, including consulting and taking back products from the competent authority or the notified body.

5.10.2 If the investigation event exceeds the timeline given by the competent authority, the company needs to submit a follow-up report to the competent authority to indicate the status.

5.10.3 The company shall have a final report, make a written statement of the results of the investigation and the measures taken, and submit it to the relevant competent authority. For the content of the final report, see the "accident report form".

5.10.4 The final report may include the following:

a) no measures;

b) strengthen supervision of the devices being used;

c) take corrective measures for future device production;

d) Implement safety corrective actions, such as systematic withdrawal of products and advisory notices.

5.11 The contact procedure between the Company and the EU authorized representative.

5.11.1 Name, address and contact information of the EU authorized representative:

Name:	Prolinx GmbH
Add:	Brehmstr. 56, 40239, Duesseldorf, Germany
Tel:	0049 211 3105 4698
Fax:	0049 211 9367 2099
Contact Person:	Mr. Nianzhuang Liu
Dimdi Code:	DE/0000045300
Vat:	DE815059178
Competent Authority Name:	Federal Institute for Drugs and Medical Devices (BfArM)
Competent Authority Code:	DE/CA20
E-mail:	med@eulinx.eu

5.11.2 What the company should do:

a) Ensure that the technical documentation for each type of CE marked product is provided to the EU authorized representative as the latest valid version.

b) In the event of a serious accident in the European Union, the cause shall be investigated with the EU authorized representative in a timely manner, and the initial

report, investigation results, and final report shall be completed and transmitted to the EU authorized representative.

c) Serious accidents occurring outside the European Union should also promptly notify authorized representatives after completing the above work.

d) In order to ensure the modification of the documents and the release of the notice, the company's international registered personnel shall maintain the latest postal address of the authorized representative of the EU (including other regions). Agreements with authorized representatives of the European Union should also specify effective means of transmitting documents or other information.

5.11.2 What EU Authorized Representatives Should Do:

a) The authorized representative of the European Union shall be responsible for registering the products that the company expects to bear the CE mark with the competent authority of the country where it is located.

b) The technical documentation of each CE-marked product of the company shall be kept for a period of five years after the last batch of products leaves the factory.

c) The company shall be notified in a timely manner of the competent authority, customer complaints or any other information related to CE-marked products occurring in the European Union.

d) Assist the company to deal with related accidents of medical devices, and report the initial report, investigation results and final report to the competent authority of the country where it is located.

6 Related documents：

Medical Device Directive IVDD 97/89 / EC;

Medical Device Alert System Guidelines MED DEV 2.12 / 1 rev8

7 Related records：

《Manufacturer`s Incident Report》

《Field Safety Corrective Action》