**Post-market surveillance Plan**

**Product Name:** **{产品名称}**

***【本处填写产品名称，需要确保全篇技术文档及报告等的名称一致】***

**Model:** **{产品型号1}、{产品型号2}、{产品型号N}**

***【需要罗列本次认证的所有产品型号清单，如型号很多，可以采用另外附件文档的方式给出】***

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{XXXX公司}

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# 1 Purpose

{填写PMS计划的目的}

*（参考示例：The purpose of this PMS Plan is to collect and review experience that gained from devices they place on the market, make available on the market or put into service, to supervise the post market devices and to identify if any necessary corrective or preventive actions need to be applied immediately in order to protect the safety and health of patients or users.）*

# **2 Scope**

{填写PMS计划使用范围}

*（参考示例：This PMS plan is applicable to the post marketing surveillance process of the CE marked product (Medical Isolation Goggles) that produce by our company..）*

# **3 Duties**

**3.1 Manufacturers**

|  |  |
| --- | --- |
| position and/or Department | Responsibilities |
| {职位和/或部门} | {职责} |
| *（参考示例：Director*  *Sales Department）* | *（参考示例：The Sales Department shall be responsible for collecting and summarizing the information from complaint information after post market, feed back from sales representatives, reports from regulatory authorities, literature reviews, service/repair information and reporting those information to management representative. ）* |
| *（参考示例：Management Representative*  *Quality Department）* | *（参考示例：After receiving the feedback from the sales department, arrange and organize the relevant departments to analyze, investigate and deal with the problems generated to determine whether any necessary corrective or preventive measures need to be taken immediately, update the relevant technical documents and report to the General Manager, the EU Authorised Representative, the Notified Body and the Competent Authority.）* |
| *（参考示例：Director*  *Quality Department）* | *（参考示例：Assist the management representative's work and participate in the investigation of the problem.）* |
| *（参考示例：General Manager Department）* | *（参考示例：Responsible for advisory notice, product recall, emergency handling and approval of related issues and reports.）* |

**3.2 Authorised Representative**

{对授权代表的职责进行描述}

*（参考示例：When receiving customer complaints or other information related to the use of the devices after put on the market, notify the manufacturer and assist the manufacturer to deal with those problems, and submit initial reports, findings and final reports to the competent authorities of the country in the EU.）*

**3.3 Distributor**

{对经销商的职责进行描述}

*（参考示例：Deliver customer complaints and other information related to the use of the devices after put on the market to the manufacturer, and keep the sales records of the products）*

# **4.Working Plan**

**4.1 Definitions**

**4.1.1 Authorised Representative：**means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation.

**4.1.2 Corrective Action：**means action taken to eliminate the cause of a potential or actual non-conformity or other undesirable situation

**4.1.3 Field Safety Corrective Action：**means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market

**4.2 Information Collection**

4.2.1 Sales department could gather, record and analyse relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.

4.2.2 Information after the device on the market: expert users groups, customer surveys, customer complaints and warranty claims, post CE-market clinical trials, literature reviews, user feed-back other than complaints, either direct to manufacturer or via sales force, device tracking/implant registries, user reactions during training programmes ect.

4.2.3 Distributor and Authorised Representative should collect customer complaint information in time, and other information related to the use of the devices after put on the market, and deliver it to the sales department.

4.2.4 If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned.

4.2.5 Sources of PMS information：

- expert users groups (focus groups)

- customer surveys

- customer complaints and warranty claims

- post CE-market clinical trials

- literature reviews

- user feed-back other than complaints, either direct to manufacturer or via sales force

- device tracking/implant registries

- user reactions during training programmes

- other bodies (e.g. the CA)

- the media

- experience with similar devices made by the same or different manufacturer

- maintenance/service reports and

- retrieval studies on explants or trade-ins

- in-house testing

- failure analysis

4.2.6 Possible achievements of a manufacturer PMS system

- detection of manufacturing problems

- product quality improvement

- confirmation (or otherwise) of risk analysis

- knowledge of long-term performance/reliability and/or chronic complications

- knowledge of changing performance trends

- knowledge of performance in different user populations

- feedback on indications of use

- feedback on instructions for use

- feedback on training needed for users

- feedback on use with other devices

- feedback on customer satisfaction

- identification of vigilance reports

- knowledge of ways in which the device is misused

- feedback on continuing market viability

4.2.7 Data gathered shall in particular be used:

1. to update the benefit-risk determination and to improve the risk management;
2. to update the design and manufacturing information, the instructions for use and the labelling;

(c) to update the clinical evaluation;

(d) to update the summary of safety and clinical performance;

(e) for the identification of needs for preventive, corrective or field safety corrective action;

(f) for the identification of options to improve the usability, performance and safety of the device;

(g) when relevant, to contribute to the post-market surveillance of other devices; and

(h) to detect and report trends in accordance with vigilance system.

**4.3 Post-market surveillance plan**

{填写上市后的监管计划}

*（参考示例：Quality department shall be responsible for drawing up post-market surveillance plan, this plan should prove that it fulfil the obligations stipulated in the coordination assessment process of clinical research.*

*(a) address the collection and utilization of available information*

*-Information relate to serious incident, including information from PSURs, and field safety corrective action；*

*-records referring to non-serious incidents and data on any undesirable side-effects;*

*-information from trend reporting;*

*-relevant specialist or technical literature, databases and/or registers;*

*-information, including feedbacks and complaints, provided by users, distributors and importers; and*

*-publicly available information about similar medical devices.*

*After collect the available information, The relevant personnel should fill in the below Table.）*

***Table 1 PMS information collection and assessment***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ***Items*** | ***Sources of PMS information*** | ***Description*** | ***Investigation***  ***(analysis) Results*** | ***Measurements*** | ***New risks identification (Y/N)*** | ***Comments*** |
| *Manufacture problem* |  |  |  |  |  |  |
| *quality improvement* |  |  |  |  |  |  |
| *Determine the result of risk management or on the contrary* |  |  |  |  |  |  |
| *Long-term performance, reliability, and/or chronic complications* |  |  |  |  |  |  |
| *performance trend* |  |  |  |  |  |  |
| *Performance different when using by different population* |  |  |  |  |  |  |
| *Feedback about product Indications for use* |  |  |  |  |  |  |
| *Feedback about user’s manual* |  |  |  |  |  |  |
| *Feedback about User training needs* |  |  |  |  |  |  |
| *Feedback about product using combined with other medical device* |  |  |  |  |  |  |
| *C[ustomers](D:/Program%20Files/Youdao/Dict/6.3.69.8341/resultui/frame/javascript:void(0);) [satisfaction](D:/Program%20Files/Youdao/Dict/6.3.69.8341/resultui/frame/javascript:void(0);) [degree](D:/Program%20Files/Youdao/Dict/6.3.69.8341/resultui/frame/javascript:void(0);)* |  |  |  |  |  |  |
| *Vigilance report* |  |  |  |  |  |  |
| *Product User error* |  |  |  |  |  |  |
| *Feedback about product Continued viability* |  |  |  |  |  |  |

）

* + 1. The main contents of post-market surveillance plan:

{填写上市后监管计划的主要内容}

*（参考示例：(b.1) proactive and systematic process to collect any information referred to in point (a)*

*The process shall allow a correct characterisation of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market;*

*The corresponding process can be applied to collect the available information, but not limited to:*

*Arrange relevant person responsible for periodical analysis the information referred to in point (a) , respectively, and evaluate and conclude that if the information had effect on performance of the devices and if the information allows a comparison to be made between the device and similar products available on the market;*

*(b.2) effective and appropriate methods and processes to assess the collected data*

*The methods and processes to assess the collected data can be referred to <clinical evaluation report>*

*(b.3) suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit risk analysis and of the risk management*

*The indicators and threshold values that shall be used in the continuous reassessment of the benefit risk analysis and of the risk management can be referred to <Risk management Control Procedures>,<Risk management document> ,<clinical evaluation report>*

*(b.4) effective and appropriate methods and tools to investigate complaints and analyse market-related experience collected in the field*

*The methods and tools to investigate complaints and analyse market-related experience collected in the field can be referred to < Service Control Program>, <clinical evaluation report>*

*(b.5) methods and protocols to manage the events subject to the trend report; including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period*

*The methods and protocols to manage the events subject to the trend report can be referred to < Continuous improvement procedures><Adverse event handling and reporting control procedures><Monitor and measure equipment control procedures>*

*(b.6) methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users*

*The methods and protocols to communicate with competent authorities, notified bodies, economic operators and users can be referred to < Feedback control program>*

*(b.6) reference to procedures to fulfil the manufacturers obligations laid down in Articles 83, 84 and 86*

*The procedures to fulfil the manufacturers obligations laid down in Articles 83, 84 and 86 is referred to < Post-market surveillance control Procedure>*

*(b.7) systematic procedures to identify and initiate appropriate measures including corrective actions*

*The procedures to identify and initiate appropriate measures including corrective actions can be referred to < Corrective and Preventive Measures Control Procedures>*

*(b.8) effective tools to trace and identify devices for which corrective actions might be necessary*

*The tools to trace and identify devices for which corrective actions might be necessary can be referred to <Corrective and preventive action control procedures><Vigilance System Control Procedures>*

*(b.8) a PMCF plan, or a justification as to why a PMCF is not applicable*

*Because the device have been tested according to EN166，GB 14866, and comply with these standards. The safety and performance of the device can be verified.*

*In additional, the technology of the device is a long-standing technology, and the device had performed clinical evaluation, we conduct appropriate post-market surveillance activities. And we have collected many clinical data to conduct clinical evaluation, including clinical literature, clinical experience. The clinical evaluation report has been explained the long-term safety and clinical performance of the device.*

*So，the PMCF studies were no required for the device.）*

**4.4 Periodic safety update report**

{对PSUR报告的要求进行描述}

*（参考示例：Throughout the lifetime of the device concerned, that PSUR should set out:*

*(a) the conclusions of the benefit-risk determination;*

*(b) the main findings of the PMCF; and*

*(c) the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.*

*Manufacturers of class IIa devices shall update the PSUR when necessary and at least every two years.)*

# **5. Related documents**

{填写与PMS相关的文档}

*（参考示例：Post-market surveillance control Procedure*

*Corrective and Preventive Measures Control Procedures*

*Vigilance System Control Procedures*

*Advisory Notice Control Procedures*

*Risk management Control Procedures*

*Measurement, Analysis and Improvement process management control procedures*

*External communication control procedures*

*PMCF plan)*