Post-market surveillance Report

**Product Name: *{填写申报产品名称 }***

**Model:*{填写申报产品的具体型号}***

**Document No.: *{填写本文档编号}***

**Edition: *{填写本文档版本号}***

Drafted by: Date: ***{填写本文档编写日期}***

Checked by: Date: ***{填写本文档审核日期}***

Approved by: Date: ***{填写本文档批准日期}***

***{填写申请者的企业名称}******（参考示例：Shenzhen Hlongmed Biotech Co.,Ltd.）***

**Revision records:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Edition** | **Effective Date** | **Summary of revision** | **Approved by** | **Checked by** | **Drafted by** |
| *{填写具体的版本号}* | *{填写对应版本的有效日期}* | *{对版本进行简要描述}* | *{填写文件批准人姓名}（参考示例：San Zhan）* | *{填写文件审核人姓名}（参考示例：Si Li）* | *{填写文件起草人姓名}（参考示例：Wu Wang）* |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**1 Purpose**

*{填写PMS报告的目的}*

*（参考示例：The purpose of this PMS report 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报告的适用范围}*

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

1. **Duties**
	1. **Manufacturers**

*{对制造商各部门的职责进行描述}*

*（参考示例：*

|  |  |
| --- | --- |
| *position and Department* | *Responsibilities* |
| *Director**Sales Department* | *The Sales Department shall be responsible for collecting and summarizing the information from complaint information after post market, feedback from sales representatives, reports from regulatory authorities, literature reviews, service/repair information and reporting this information to management representative.*  |
| *Management Representative**Quality Department* | *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.* |
| *Director**Quality Department* | *Assist the management representative's work and participate in the investigation of the problem.* |
| *Director**General Manager Department* | *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 Result of PMS information collection and assessment**

4.3.1 Result of PMS information collection

*{列出收集到的PMS信息}*

*（参考示例：The PMS information is collected and assessed according to PMS plan. The result of PMS information collection is as below.*

*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* | */* | */* | */* | */* | */* | */* |
| *Customers satisfaction degree* | */* | */* | */* | */* | */* | */* |
| *Vigilance report* | */* | */* | */* | */* | */* | */* |
| *Product User error* | */* | */* | */* | */* | */* | */* |
| *Feedback about product Continued viability* | */* | */* | */* | */* | */* | */* |

*）*

4.3.2 Result of PMS information collection for similar product

*{放入收集到的相似产品的PMS信息}*

4.3.2.1NMPA

*{搜集申报产品的同类产品或相似产品在NMPA的PMS信息}*

*【需要证据，如截图】*

4.3.2.2 Gov.UK

*{搜集申报产品的同类产品或相似产品在英国的PMS信息}*

*【需要证据，如截图】*

4.3.3 Result of PMS information assessment

*{放入PMS信息评估结果}*

**4.4 PMCF plan , or a justification as to why a PMCF is not applicable**

*{若PMCF计划，或PMCF不适用的话，请给出合理的理由}*

*（参考示例：Because the device has 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.）*

**4.5 PMS Report**

*{放入PMS报告}*

*（参考示例：A PMS report has been prepared to summarize the results and conclusions of the analysis of all of the data from the market as above. Every data gathered from the PMS has been assessed.*

*And the data gathered are used to evaluate if it needs*

*to update the benefit-risk determination and to improve the risk management;*

*to update the design and manufacturing information, the instructions for use and the labelling;*

*to update the clinical evaluation;*

*to update the summary of safety and clinical performance;*

*for the identification of needs for preventive, corrective or field safety corrective action;*

*for the identification of options to improve the usability, performance and safety of the device;*

*when relevant, to contribute to the post-market surveillance of other devices; and*

*to detect and report trends in accordance with vigilance system.*

*Cause no adverse events and/or feedback about the Medical Isolation Goggles are collected during the PMS, so there is no need to update the risk management report, user manual and/or clinical evaluation report. Meanwhile, we need to keep quality system continuously effective.）*

