

Measures for Administration of Medical Device Recall

Chapter I General Provisions

Article 1 In order to strengthen the supervision and management of medical devices and protect human health and safety, these Measures are formulated in accordance with *the Regulation on the Supervision and Administration of Medical Devices* and *the Special Rules of the State Council on Strengthening the Supervision and Management of the Safety of Food and Other Products*.

Article 2 These Measures shall apply to the recall of medical devices sold in the territory of the People's Republic of China as well as the supervision and management thereof.

Article 3 The expression ‘medical device recall’, within the context of these Measures, means a medical device manufacturer’s action of giving a warning about, examining, repairing, re-labelling, revising or improving the specifications of, upgrading software for, replacing, recalling or destroying a certain category, type or batch of sold defective products in accordance with the procedures provided to eliminate the defect.

Article 4 The term ‘defect’, within the context of these Measures, means any unreasonable risk caused by a medical device in normal use that may endanger human health or safety.

Article 5 A medical device manufacturer is the subject that shall control and eliminate a product defect and be responsible for the safety of a product manufactured thereby.

Article 6 A medical device manufacturer shall establish and improve its medical device recall system, collect information about the safety of medical devices, investigate and evaluate the potential defective medical devices, and issue a timely recall on the defective medical devices in accordance with the provisions of these Measures.

A medical device trading company or a unit using the device shall assist the medical device manufacturer in fulfilling the obligations of recall, shall communicate and provide feedback on the medical device recall in a timely manner in accordance with the requirements of the recall plan, and controlling and recovering the defective medical devices.

Article 7 Should a medical device trading company or a unit using the device find any defect in the medical device that it trades or uses, it shall immediately suspend the sale or use of the said device, promptly notify the manufacturer or supplier, and report it to the drug regulatory authority of the province, autonomous region or municipality directly under the

central government where the trading company or unit using the device is headquartered. If the unit using the device is a medical institution, the case shall also be reported to the health administration authority of the province, autonomous region, or municipality directly under the central government where the unit is headquartered.

Upon receipt of such a report, the drug regulatory authority of the province, autonomous region or municipality directly under the central government where the medical device trading company or unit using the device is headquartered shall timely notify its counterpart in the province, autonomous region or municipality directly under the central government where the manufacturer is headquartered.

Article 8 The drug regulatory authority of the province, autonomous region or municipality directly under the central government where the manufacturer recalling medical devices or the designated agent of an overseas manufacturer of imported medical devices in the territory of China is headquartered shall be responsible for the supervision and management of medical device recalls, while its counterparts in other provinces, autonomous regions or municipalities directly under the central government shall provide cooperation and assistance for the recalls of medical devices in the jurisdiction thereof.

The State Food and Drug Administration shall oversee the management of medical device recalls nationwide.

Article 9 The State Food and Drug Administration and the drug regulatory authority of the province, autonomous region or municipality directly under the central government shall establish a medical device recall information communication and disclosure system to communicate the relevant information to the health administrative authorities of the same level in a timely manner, and take effective measures to disclose the information about defective medical devices and their recalls to the public.

Chapter II Investigation into and Evaluation of Medical Device Defects

Article 10 A medical device manufacturer shall establish and improve its medical device quality management system and its medical device adverse event monitoring system, collect and record the quality problems of, and the adverse events relating to, medical devices, analyze the information collected, and investigate into the possible defects of medical devices.

A medical device trading company or unit using the device shall work with the manufacturer in carrying out investigations into defects of the devices, and provide relevant information.

Article 11 The medical device manufacturer shall be required to timely submit the collected information on adverse events of the medical device to the drug regulatory authorities, which may analyze or investigate into the said information or the possible defects, while the medical device manufacturer, trading companies and units using the device shall provide assistance for the investigation.

Article 12 Evaluation of the defects of a medical device shall include the following:

- (1) whether any fault or damage occurs during the use of the medical device;
- (2) whether the device will cause any injury when used under the current circumstances, and whether there is any scientific literature, study, relevant test or verification that explains the causes of injury;
- (3) territorial scope and population characteristics of the injury;
- (4) the extent of the damage to human health;
- (5) probability of injury;
- (6) short- and long-term consequences of the injury;
- (7) other factors that may cause injuries.

Article 13 According to the severity of medical device defects, recalls are divided into:

- (1) Class I Recall: The use of the medical device is very likely to cause a severe health hazard;
- (2) Class II Recall: The use of the medical device could possibly cause a temporary or irreversible health hazard;
- (3) Class III Recall: The use of the medical device is not very likely to cause adverse health consequences, but it is still necessary to recall the device.

The medical device manufacturer shall design and implement an appropriate recall plan based on the recall classification and the sale and use of the medical device.

Chapter III Voluntary Recall

Article 14 If, after the investigation and evaluation as per Articles 10 and 12 has been concluded, it is ascertained that the medical device is defective, the manufacturer shall immediately decide to recall it.

In case of extraterritorial recall, the overseas manufacturer of medical devices shall request its designated agent in China to timely report it to the State Food and Drug Administration. In the case of recall in the territory of China, its designated agent in China shall be responsible for the specific implementation of recall in accordance with these Measures.

Article 15 Once deciding to recall any medical device, the manufacturer shall notify the relevant trading companies, units using the device or users within one (1) day in the case of a Class I recall, or three (3) days in the case of a Class II recall, or seven (7) days in the case of a Class III recall.

The recall notice shall at least cover the following:

- (1) Basic information such as the name and batch of the medical device;
- (2) The reasons for the recall;
- (3) The requirements for the recall: in case of an immediate suspension of the sale and use of the product, a recall notice shall be forwarded to the relevant trading companies or units using the device;
- (4) The disposal of the medical device recalled.

Article 16 Once deciding to recall any medical device, the manufacturer shall immediately inform, in writing, the drug regulatory authority of the province, autonomous region or municipality directly under the central government where it is headquartered, and complete the *Report of Medical Device Recall Event* (Annex 1) within five (5) days, and at the same time submit the investigation and evaluation report and the recall plan to the same authority to be put on record.

The drug regulatory authority of the province, autonomous region or municipality directly under the central government shall timely submit the information about Class I Recall to the State Food and Drug Administration.

Article 17 The investigation and evaluation report shall include the following:

- (1) The details of the medical device recalled, including basic information such as the name and batch thereof;
- (2) The reasons for the recall;
- (3) Results of the investigation and evaluation;
- (4) Classification of the recall.

The recall plan shall include the following:

- (1) The production and sales of the medical device and the quantity to be recalled;
- (2) The specific recall measures, including the implementation organization, scope and time limits;
- (3) Recall information disclosing channel and scope;
- (4) The expected effects of the recall;
- (5) The disposal of the medical device recalled.

Article 18 The drug regulatory authority may organize experts when appropriate to assess the recall plan submitted by the manufacturer, and request the manufacturer to take more effective measures such as increasing the recall class, expanding the recall scope, shortening the recall time or changing the disposal of products recalled, in case the measures taken are deemed to be unable to eliminate the defects of the medical device.

Article 19 In case of changing the recall plan, the medical device manufacturer shall timely report the change to the drug regulatory authority to be put on record.

Article 20 During the implementation of the recall, the manufacturer shall regularly submit the *Report on Implementation of the Recall plan* (Annex 2) to the drug regulatory authority according to the recall plan, and report the implementation of the recall plan.

Article 21 The medical device manufacturer shall keep detailed records of the disposal of medical devices, and report to the drug regulatory authority of the province, autonomous region or municipality directly under the central government where it is headquartered. In the case of product defects that can be eliminated by giving a warning about, examining, repairing, relabelling, revising the specifications of, upgrading software for, replacing, recalling or destroying defective products, the above can be completed on location. If destruction is necessary, the defective product should be destroyed under the supervision of the drug regulatory authority at the location where the destruction will take place.

Article 22 After the recall is completed, the manufacturer shall evaluate the effect of the recall, and submit the *Summary Report of Medical Device Recall* to the drug regulatory authority within ten (10) days of the completion.

Article 23 The drug regulatory authority shall review the report and evaluate the effect of the recall within ten (10) days of the receipt of the summary report. The review and evaluation conclusions shall be presented in writing to the medical device manufacturer, with a copy sent to the competent health administrative authority.

If the review and evaluation find that the recall is not done thoroughly, and fails to effectively remove all the defects, the drug regulatory authority shall require the manufacturer to re-recall.

Chapter IV Compulsory Recall

Article 24 Where the investigation and evaluation finds any defect mentioned in Article 4, and where the medical device manufacturer should have voluntarily recalled the product but failed to do so, the manufacturer shall be ordered to recall the said device.

When necessary, the drug regulatory authority shall require the medical device manufacturer, trading companies or units using the device to immediately suspend the sale or use of, and inform the users to immediately suspend the use of, the medical device.

Article 25 Once deciding to order a recall, the drug regulatory authority shall serve a compulsory recall notice to the medical device manufacturer or the domestic agent of manufacturer of imported medical devices, and the notice shall include the following:

- (1) The details of the medical device recalled, including basic information such as the name and batch thereof;
- (2) The reasons for the recall;
- (3) Results of the investigation and evaluation;
- (4) The requirements for the recall, including the scope and time limits.

Article 26 Upon the receipt of the compulsory recall notice, the manufacturer shall request the medical device trading companies, units using the device or users to develop and submit the recall plan, and organize the implementation thereof in accordance with the provisions of Articles 15 and 16 hereof.

Article 27 The manufacturer shall report the relevant circumstances of the medical device recall to the drug regulatory authority, and carry out the follow-up disposal of the devices in accordance with the provisions of Articles 19, 20, 21 and 22 hereof.

The drug regulatory authority shall review the *Summary Report of Medical Device Recall* submitted by the manufacturer, and evaluate the effects of the recall, and timely inform the competent health administrative authority. If the review and evaluation find that the recall has not been done thoroughly, and has failed to effectively remove all the defects, the drug regulatory authority shall require the manufacturer to re-recall.

Chapter V Legal Liability

Article 28 Where the drug regulatory authority confirms that the defects of medical devices on the market are caused by the manufacturer in violation of laws, regulations and rules, administrative penalties shall be imposed on the manufacturer. If the manufacturer has voluntarily taken recall measures to eliminate or alleviate the consequences, a lighter or mitigated penalty shall be imposed on them in accordance with the *Administrative Penalty Law*. Where the offense is minor and is promptly corrected without any harmful consequences, the manufacturer may be exempt from punishment.

A medical device manufacturer's act of recall does not exempt it from other legal liabilities.

Article 29 Where a medical device manufacturer violates the provisions of these Measures by failing to voluntarily recall the known defective medical devices, the manufacturer shall be ordered to recall the devices, and a penalty three times the value of the medical devices that should have been recalled shall be imposed on them. In cases where serious consequences have been caused, the original license issuing authority shall revoke the medical device registration certificate, or even the *License for Medical Device Manufacturer*.

Article 30 Where a medical device manufacturer violates the provisions of Article 24 by refusing to recall the medical devices, a penalty three times the value of the medical devices that should have been recalled shall be imposed on them. In cases where serious consequences have been caused, the original license issuing authority shall revoke the medical device registration certificate, or even the *License for Medical Device Manufacturer*.

Article 31 Where a medical device manufacturer violates the provisions of Article 15 by failing to request the trading companies, the units using the device, or the users to suspend the sale or use of the medical devices to be recalled, the manufacturer shall be given a warning and be charged to make corrections, and a penalty less than RMB30,000 shall be imposed on them.

Article 32 Where a medical device manufacturer violates the provisions of Articles 18, 23(2) and 27(2) by failing to take corrective measures or to re-recall the medical devices as required by the drug regulatory authority, the manufacturer shall be given a warning and be charged to make corrections, and a penalty less than RMB30,000 shall be imposed on them.

Article 33 Where a medical device manufacturer violates the provisions of Article 21, the manufacturer shall be given a warning and be charged to make corrections, and a penalty less than RMB30,000 shall be imposed on them.

Article 34 The medical device manufacturer shall be given a warning and be charged to make corrections, and a penalty less than RMB20,000 shall be imposed on them, in one of the following circumstances:

- (1) failing to establish the medical device recall system;
- (2) refusing to assist the drug regulatory authority in making investigations;
- (3) failing to submit the *Report of Medical Device Recall Event*, the investigation and evaluation report and the recall plan, the medical device recall progress report or the summary report, in accordance with the provisions of these Measures;
- (4) failing to file the change to the recall plan with the drug regulatory authority for their records.

Article 35 Where a medical device trading company or a units using the device violates the provision of Article 7(1) of these Measures, the company or unit shall be ordered to stop selling or using the defective medical devices, and a penalty of RMB1,000-50,000 shall be imposed on them. In cases where there are serious consequences, the original license issuing authority shall revoke the *License for Medical Device Trading Company*.

Article 36 Where a medical device trading company or unit using the device refuses to work with the manufacturer or the drug regulatory authority to conduct an investigation into the defects of the medical device, or refuses to assist the manufacturer in recalling the defective medical devices, the company or unit shall be given a warning and ordered to make corrections. In cases where there is a refusal to make corrections, a penalty less than RMB20,000 shall be imposed on them.

Article 37 In cases where the drug regulatory authority and its staff fail to perform their duties or abuse their authority, the case shall be addressed in accordance with relevant laws and regulations.

Chapter VI Supplementary Provisions

Article 38 In cases where the medical device manufacturer, trading company or unit using the device violates these Measures and causes damages to the users of the medical device, it shall be liable for compensation according to the law.

Article 39 These Measures shall go into effect as of [date].

Annex 1:

Report of Medical Device Recall Event

Name of the Product		Registration Certificate No.	
Manufacturer			
Responsible Unit or Person and their Contacts in China			
Contacts for Recall			
Scope of Application of the Product			
Country/Region Involved		Model and Specifications of the Product Involved	
Quantity of the Manufactured (or Imported) Products Involved		Sales of the Product Involved in China	
Identification (e.g. Batch No.)			
Outline of Reasons for Recall			
Outline of Corrective Actions			

Reporting Unit: (Seal)

Responsible Person: (Signature)

Reported by: (Signature)

Date:

Annex 2:

Report on the Implementation of the Recall Plan

Name of the Product		Registration Certificate No.	
Manufacturer			
Agent in China and Responsible Person and their Contacts			
Contacts for Recall			
Notification	Receiver Responsible for Communication for Recall	Number of People to Be Notified	
		Number of People Notified	
		Time of Notice	
		Means of Notifying	
	Other Receivers	Number of People to Be Notified	
		Number of People Notified	
		Time of Notice	
		Means of Notifying	
Completion	Quantity of Products to Be Recalled		
	Quantity of Products Recalled		
	Effective Inspection		
Disposal of Recalled Products			
Estimated Time for Completing the Recall			

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Reporting Unit: (Seal)

Responsible Person: (Signature)

Reported by: (Signature)

Date: