上海季美进出口有限公司

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Urgent Field Safety Notice

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Nebulizer Masks

After The Aerosol Mask is connected to the compressed air source,

Partial nebulizers cannot be nebulized or partial nebulization

Our Records indicate that your facility may have received the following product:

Table 1.Nebulizer Masks Affected Product(s)

Size	Quantity	Catalog Number	Lot Number	expiration Date
Adult elongated	10,000PCS	KM-KS028	20170428	20220427
Pediatric elongated	5,000PCS	KM-KS028	20170428	20220427

Description of the problem:

After The Aerosol Mask is connected to the compressed air source, Partial nebulizers cannot be nebulized or partial nebulization

Sample test results:

We received six Defective samples(Nebulizers),and the results are as follows:

Pre test liquid	Liquid after detection	Detection time	Nebulization rate
20.9g	20.0g	2min	0.45g/min
20.7g	20.0g	2min	0,35g/min
20.0g	19.2g	2min	0.40g/min
21.3g	20.4g	2min	0.45g/min

21.8g	20.6g	2min	0.60g/min
21.0g	19.91g	2min	0.54g/min

Internal investigation demonstrates:

- It is verified that the problem nebulizers are produced by our injection workshop in the first week of the relocation to the new factory area. When the new injection workshop was produced in the first week, PQC was not in place.

- The main reason for customer complaints is the fact that the injection regrind material in the green middle cover of nebulizer is not cleaned in time, When the regrind material is dry, it generates about 1.5mm removable flashing on the middle cover. When the nebulizer is added to the liquid for aerosol, the injection regrind material will plug the small holes in the middle cover of nebulizers, However, the air source continues to supply the nebulizers pressure from the oxygen connection tube. The air flow is blocked by the removable flashing hole in nebulizers, and can not flow smoothly into the mask. so the air pressure will lead to oxygen connecting tube from the nebulizers bottom off and resulting in lower nebulization rate or no nebulization, The proportion of this kind of problem is about 2.5%. The nebulization is completely normal after removing the injection regrind material.

Risk To Health:

- Nebulizers has low atomization rate and small amount of fog, which will cause atomization time too long. It will affect the nebulization treatment effect and comfort degree of patients.

- The blockage of the Nebulizers will cause air blockage, and Nebulizers can not atomized normally, which will lead to deterioration of symptoms in clinical operation.

- The air flow is blocked by the removable flashing hole in nebulizers, and can not flow smoothly into the mask. The oxygen connection tube can't be pressed tightly into the Nebulizers due to air pressure, and it will fly out and cause injury.

Actions to be Taken by the Customer:

- Before clinical use, please check whether the nebulization effect is normal;

- It is suggested that when the clinic is used, the gas flow rate should be controlled at 4-6L/min according to the atomization condition of the drug.

- If it is a nebulizer cannot be nebulized or partially nebulized, it is forbidden to use it.

According to the “Defective products recall regulations”, our company decide to recall the product described in this notice, in order to eliminate the hidden danger of the product and protect the benefit of your company.

Specific contents of the recall measures (external):

- Recall 15,000pcs defective products immediately and unconditionally, compensate the customer with the same

  amount of product at the same time, to ensure the normal supply of the products and meet customer demand. The cost of the recall and the freight charges are all bear by our company, customer don’t need to bear any fee.

- The implementation plan of the recall measures (please describe in detail): Starting from this notice,all products that have been sent to the hospital and warehouse inventory are stop using and recall to the Chinese factory to process. The related costs are bear by the factory.

- After receiving this notice, Please communicate with us in time, to ensure the recall of all products are smoothl y, and avoid to cause a wide range of negative effects.

Preventive and corrective actions(Internal Company)：

- To strengthen the maintenance of nebulizer moulds to ensure that the moulds are in good condition,strengthen the control of related production parameters in injection molding process, and add two QC in the injection par t, detect the nebulization result every half an hour.

- During the production and assembly, we detect 100% of the nebulizers, In addition to increase two PQC, rando m inspection every hour, and detect the nebulizers in batches every day, which must be not less than 200PCS. 100% detect the nebulizers can basically identify and eliminate the possible risks of the nebulizers.Our company is the only one in China with 100% inspection of nebulizers, which has been implemented in August 2017.

- Strengthen the training of relevant personnel, so that everyone can know the possible risks of the products and the core points of possible problems, so as to ensure that related problems will not occur again.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

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For and on behalf of
上海季美进出口有限公司
SHANGHAI KINMED IMPORT & EXPORT CO., LTD.

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Authorized Signature(s)

Shanghai Kinmed Import & Export Co., Ltd.
Managing Director: Zhong Zhigang
Apr.03, 2018