Guangzhou AMK Medical Equipment Co.,Limited

Add: 4th Floor, No. B14, Huachuang Industry Park Jinshan Cun, Shiqi Town, Panyu District
CN-511450 Guangzhou

URGENT field safety notice

Recall on affected devices

Endotracheal tube-Set for single use

Date: 23.10.2023

Issuer/ Manufacturer:

Guangzhou AMK Medical Equipment Co., Ltd.
4th Floor, No. B14, Huachuang Industry Park
Jinshan Cun, Shiqi Town, Panyu District

Addressee: customers of the EU Importer, which received the affected batch.

model	refrence	Device type	batch	Expiry date
061-EFSW-060	SY0106-A060	Endotracheal tube-Set for single use	22/502363	2027-03-30
061-EFSW-075	SY0106-A075	Endotracheal tube-Set for single use	22/502363	2027-03-30
061-EFSW-080	SY0106-A080	Endotracheal tube-Set for single use	22/502363	2027-03-30
061-EFSW-085	SY0106-A085	Endotracheal tube-Set for single use	22/502363	2027-03-30

Description of the product problem and the probability of problem arising:

In a user report, it was determined that the designated product *„Endotracheal tube-Set for single use"*, model 061-ESFW-080 of the mentioned batch 22/502363, the included mandrins aren´t easily removed.

The error has not been reproduced by the manufacturer.

Based on the results of internal tests at the manufacturer as well as the EU importer, the defect can be limited to the listed batch of this product. No other batch of this product is affected. As a precaution, all sizes of the same product from this batch are being recalled. The error could not be reproduced so far.

Action To Be Taken by the User:

1. Check all stocked products for the affected REF-Code and Batch-numbers.

2. Forward this information to any other party, that you supplied this product to (i.e., your customers).

3. If you or your customer(s) have any affected goods in your stock, please ensure that the relevant products are quarantined and no longer in use. Please notify us about your relevant stock via the link below.

4. Please provide feedback regarding your stock via the link below until November 24th 2023.

5. Please destroy your affected stock. By sending your report-form you confirm the accuracy of your reported quantities aswell as their destruction. Please implement the measures immediately.

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6. After providing your Report-Form, you will receive a credit memo from Wolfram Droh GmbH.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The German federal institute for pharmaceuticals and medical products has received urgent field safety notice.

Contact EU-importer:

Wolfram Droh GmbH

[redacted]

We regret the inconvenience caused and apologise for this.

Yours sincerely

Guangzhou AMK Medical Equipment Co., Ltd