

Urgent Field Safety Notice

Disposable Sampling Swab

No.: 220426-01

Advice given by MANUFACTURER regarding the use of the device.

Date: April 24, 2022

Attention: Beijing Lepu Medical Technology Co., Ltd.

Details on affected devices:

Product: Disposable Sampling Swab

Batch Number: 21CY05001

Product model: KQ001

Description of the problem:

Because this batch of products received user feedback in the use of sampling head variation, after analysis, this event is an accidental event, the defective products will not cause serious injury to patients.

Advise on action to be taken by the user:

- 1. Visual inspection of sampling head before using;*
- 2. If the sampling head is abnormal, do not continue to use it.*
- 3. If the product is abnormal, please report to the seller or manufacturer in time.*

Transmission of this Field Safety Notice:

Please send this notice to the distributor and medical institution

Contact reference person:

Liu Zhan Jun

Shenzhen KangDaAn Biological Technology Co., Ltd.

Phone: +86 755-82836262

Fax: +86 755-83426595

E-mail: 1392528868@qq.com

Address: East-1, 3rd floor, Building 2, Shunheda factory, Liuxiangdong industrial zone, Xili street, Nanshan district, Shenzhen, China

The undersign confirms that this notice has been notified the appropriate Regulatory Agency.



..... Signature