

# ZIBO QIAOSEND MEDICAL ARTICLES CO., LTD.

Add: No.88, Tianheng Road, Gaoqing County, Zibo Shandong Province, China

Tel:0086-533-6985995 Fax:0086-533-6966582

Email: [zhanghaibin@qiaosend.com](mailto:zhanghaibin@qiaosend.com)

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## **Urgent Field Safety Notice**

**Commercial name of the affected product, Extension lines for single use**

**FSCA-identifier: QSZK-202507-182-001**

**Type of action** Issue a warning to the user

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Date: 2025-08-14

Attention: End users

### **Details on affected devices:**

**Manufacturer:** Zibo Qiaosend Medical Articles Co., Ltd.

**Product:** Extension lines for single use

**Device Model:** Refer to Attachment 1

### **Description of the problem:**

Through the review of complaint data, Qiaosend found that when users use disposable extension lines in combination with other devices, if the connection parts come into contact with ethanol-based disinfectants during the usage process, there may be a risk of cracking or leakage of the connection components. Qiaosend will send FSN to customers to enhance warnings/precautions and reduce the occurrence rate of potential problems.

### **Clinical Risk Statement**

*In instances where leakage occurs, there may be a delay in procedure, treatment interruptions, exposure to hazardous drugs, and/or underdosing of medication.*

### **Advise on action to be taken by the user**

- *This product is sterile, no disinfection is needed. If other device connecting this product need disinfection with ethanol disinfectant, ensure it is dry before use. No patient follow-up actions are required if the device has already been safely used.*

### **Action to be taken by Zibo Qiaosend**

Zibo Qiaosend Medical Articles Co., Ltd. will update the labelling of all Extension lines for single use (Refer to product codes in Attachment 1) to have the following warning added:

***This product is sterile, no disinfection is needed. If other device connecting this product need disinfection with ethanol disinfectant, ensure it is dry before use.***

The product will continue to be distributed with the current label until the update is completed.

### **Transmission of this Field Safety Notice:**

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

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

### **Contact reference person:**

Zhang Haibin, Zibo Qiaosend Medical Articles Co., Ltd., China

Email: [zhanghaibin@qiaosend.com](mailto:zhanghaibin@qiaosend.com)

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency

Authorized Signatory

Name: Dou Xuefeng

Position: General Manager

Signature: 

Attachment 1: List of products

Description of products	Model code
Extension Lines for Single Use	DI-10-G
Extension Lines for Single Use	DI-10
Extension Lines for Single Use	DI-25-G
Extension Lines for Single Use	DI-25
Extension Lines for Single Use	DI-50-G
Extension Lines for Single Use	DI-50
Extension Lines for Single Use	DI-75
Extension Lines for Single Use	DI-100-G
Extension Lines for Single Use	DI-100
Extension Lines for Single Use	DI-150-G
Extension Lines for Single Use	DI-150
Extension Lines for Single Use	DI-200-G
Extension Lines for Single Use	DI-200
Extension Lines for Single Use	DI-10-3VG
Extension Lines for Single Use	DI-10-YG
Extension Lines for Single Use	L-303/10
Extension Lines for Single Use	DI-25-3VG
Extension Lines for Single Use	DI-25-YG
Extension Lines for Single Use	L-303/25
Extension Lines for Single Use	DI-50-3VG
Extension Lines for Single Use	DI-50-YG
Extension Lines for Single Use	L-303/50
Extension Lines for Single Use	DI-100-3VG
Extension Lines for Single Use	DI-100-YG
Extension Lines for Single Use	L-303/100
Extension Lines for Single Use	DI-150-3VG
Extension Lines for Single Use	DI-150-YG
Extension Lines for Single Use	L-303/150
Extension Lines for Single Use	DI-200-3VG
Extension Lines for Single Use	DI-200-YG
Extension Lines for Single Use	L-303/200