

10.5 ANNEX 5 - Template for a Field Safety Notice**Urgent Field Safety Notice****Commercial name of the affected product, Extension lines for single use****FSCA-identifier (e.g. date) QSZK-202507-182-001 2025-07-11****Type of action (e.g. chapter 4 definition of a FSCA). Issue a warning to the user**

Date: 2025-07-11

Attention: //////////////////////////////////

Details on affected devices:

Manufacturer: Zibo Qiaosend Medical Articles Co., Ltd.

Product: Extension lines for single use;

Device Model: DI-150

Lot No.: 09193

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.

Advise on action to be taken by the user:

Issue a warning to the user: Avoid contact with ethanol disinfectant during the use of this product.

Transmission of this Field Safety Notice: (if appropriate)

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. (If appropriate)

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

Name / organisation, address, contact details.

The undersign confirms that this notice has been notified the appropriate Regulatory Agency (Closing paragraph)

Signature

Template for a Field Safety Notice Customer Reply Form**Customer Reply Form**

1. Field Safety Notice (FSN) information	
FSN Reference number*	QSZK-202507-181-001
FSN Date*	2025-7-11
Product/ Device name*	Extension Lines for Single Use
Product Code(s)	DI-150
Batch/Serial Number (s)	1 2 3

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
<input type="checkbox"/>	No affected devices are available for return/ destruction	Customer to complete or enter N/A		
<input type="checkbox"/>	Other Action (Define):			

<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	Pre-filled by manufacturer/sender/requester
Customer Helpline	Pre-filled by manufacturer/sender/requester
Postal Address	Pre-filled by manufacturer/sender/requester
Web Portal	Pre-filled by manufacturer/sender/requester
Fax	Pre-filled by manufacturer/sender/requester
Deadline for returning the customer reply form*	Pre-filled by manufacturer/sender/requester

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.