FSN Ref: ECL-FSCA-005_1_XX_xx_1 FSCA Ref: ECL-FSCA



Date: 2024-05-24

Field Safety Notice Olympus EndoDis Pro

For Attention of: Vigilance manager of the facility and the users of the affected products.

Dear customer,

We ask you to please review the information in this document and follow the appropriate actions outlined in section 3. Please fill in the reply form accompanying this FSN and return it to us as soon as possible.

Thank you for your cooperation and understanding.

Best regards,

ECOLAB VIGILANCE



Field Safety Notice (FSN) Olympus EndoDis Pro Wrong shelf-life on the label

	1. Information on Affected Devices				
1.	Device Type				
	Disinfectant				
1.	2. Commercial nan	ne			
	Olympus EndoDis Pro				
1.	Primary clinical purpose of device				
	Disinfectant for PAA process in ETD system				
1.	Device Catalogu	e Number and Batch Code			
	Catalogue Number	Batch Code			
	3099120	2243AP0104			
	3100780	5233AP0204			
	3100780	3293AP0104			
	3099120	3293AP0204			
	3099120	2034AP0204			

Reason for Field Safety Corrective Action (FSCA) 2. Description of the product problem

Devices are labelled with a wrong shelf-life.

Catalogue Number	Batch Code	WRONG Shelf life (currently stated on the label)	CORRECT Shelf life (please consider this)
3099120	2243AP0104	2024-12	2024 - 10
3100780	5233AP0204	2024-12	2024 - 10
3100780	3293AP0104	2025-01	2024 - 10
3099120	3293AP0204	2025-01	2024 - 10
3099120	2034AP0204	2025-07	2025 - 05

2. 2. Hazard giving rise to the FSCA

> The expiration date printed on the label is incorrect, however, the product is currently not expired. If the product is used as per the correct shelf life as described in section 3.1. There is no patient/user risk, but Ecolab is issuing this FSCA to remove any risk that might happen if the product is used beyond the correct expiration date.

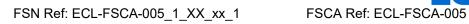
3. Type of Action to mitigate the risk

Action To Be Taken by the User 3.

☑ Identify the device

☑ Use the device as per the correct expiry date in the table below

Catalogue Number	Batch Code	CORRECT Shelf life (please consider this)
3099120	2243AP0104	2024 - 10
3100780	5233AP0204	2024 - 10
3100780	3293AP0104	2024 - 10
3099120	3293AP0204	2024 - 10
3099120	2034AP0204	2025 - 05





	2. Action To Be Taken by the Distributor		
	☑ Identify device		
	⊠ Inform Users to proceed a	ccording to the section 3.1 "Action	to be taken by the user".
		omers, block the stock and reach ouk (andre.walkowiak@ecolab.com)	ut to Global Account Manager
3.	3. By when should the action be completed?	Immediately	
3.	4. Is customer Reply Require (If yes, form attached specifyin		Yes

	4. General Information				
4.	1. FSN Type	New			
4.	2. Further advice or information already expected in follow-up FSN?	No			
4.	Manufacturer information (For contact details of local representative)	refer to page 1 of this FSN)			
	a. Company Name	Ecolab Deutschland GmbH			
	b. Address	Ecolab-Allee 1, DE-40789 Monheim			
	c. Website address	www.ecolab.com			
4.	4. The Competent (Regulatory) Authority of your country has been informed about th communication to customers.				
4.	5. List of attachments/appendices:	FSN Reply Form			
4.	6. Name/Signature	Regulatory Affairs Manager Ecolab Deutschland GmbH Director Quality Ecolab Spain Services SL			

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. (As appropriate)
Please transfer this notice to other organisations on which this action has an impact. (As appropriate)
Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.



Customer Reply Form

1. Field Safety Notice (FSN) information			
FSN Reference number	ECL-FSCA-005_1_XX_xx_1		
FSN Date	2024-05-24		
Device name	Olympus EndoDis Pro		
Product Codes and Batch Numbers	Catalogue Number Batch Code		
	3099120 2243AP0104		
	3100780 5233AP0204		
	3100780 3293AP0104		
	3099120 3293AP0204		
	3099120 2034AP0204		

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. C	3. Customer action undertaken on behalf of Healthcare Organisation			
	I confirm receipt of the Field Safety Notice and that I read and understood its content. I performed all actions requested by the FSN.	Customer to complete Customer to complete	or enter N/A	
	The information and required actions have been brought to the attention of all relevant	Customer to complete	or enter N/A	
	I have the following devices on stock – enter	Catalogue Number	Batch Code	Quantity (Packs / Bottles)
	number of devices on	3099120	2243AP0104	(11 1 11 11 11 1
	stock.	3100780	5233AP0204	
		3100780	3293AP0104	
		3099120	3293AP0204	
		3099120	2034AP0204	
	I do not have any affected devices.	Customer to complete	or enter N/A	
Print	Name	Customer print name here		
Signature Customer sign he		Customer sign here		



Date	Customer put name here

4. Return acknowledgement to sender		
Email andre.walkowiak@ecolab.com		
Deadline for returning the customer reply form	2024-06-24	

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.