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. 1. Device Type

Disinfectant

1. 2. Commercial name

Olympus EndoDis Pro

1. 3. Primary clinical purpose of device

Disinfectant for PAA process in ETD system

1. 4. Device Catalogue Number and Batch Code

Catalogue Number	Batch Code
3099120	2243AP0104
3100780	5233AP0204
3100780	3293AP0104
3099120	3293AP0204
3099120	2034AP0204

2. Reason for Field Safety Corrective Action (FSCA)

2. 1. 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

3. 1. Action To Be Taken by the User

☒ 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 according to the section 3.1 “Action to be taken by the user”. ☒ For batches not with customers, block the stock and reach out to Global Account Manager OEM – HC- André Walkowiak (andre.walkowiak@ecolab.com)	
3.	3. By when should the action be completed?	Immediately
3.	4. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes

	4. General Information	
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. 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 this 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. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A
☐	I have the following devices on stock – enter number of devices on stock.	
☐	I do not have any affected devices.	Customer to complete or enter N/A
Print Name		Customer print name here
Signature		Customer sign here

Catalogue Number	Batch Code	Quantity (Packs / Bottles)
3099120	2243AP0104	
3100780	5233AP0204	
3100780	3293AP0104	
3099120	3293AP0204	
3099120	2034AP0204	

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.