Date: 2024-07-30

Field Safety Notice (FSN)
Olympus EndoDis Pro
Wrong expiry date 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 expiry date.

Catalogue Number	Olympus Code	Batch Code	WRONG expiry date (currently stated on the label)	CORRECT expiry date (please consider this)
3099120	WD00342A	2243AP0104	*2024-12*	*2024 - 10*
3100780	WD00347A	5233AP0204	*2024-12*	*2024 - 10*
3100780	WD00347A	3293AP0104	*2025-01*	*2024 - 10*
3099120	WD00342A	3293AP0204	*2025-01*	*2024 - 10*
3099120	WD00342A	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. There is no patient/user risk associated with the product you have in stock, but you need to follow the instructions in section 3.2. We are doing this corrective action as a precaution to achieve highest standards of safety and in alignment with Olympus

3. Type of Action to mitigate the risk

3. 1. Action To Be Taken by the Distributor, Olympus

☒ Identify product in stock or distributed to users.

☒ Inform Users to proceed according to the section 3.2 “Recommended actions to be taken by the user”.

Catalogue Number	Olympus Code	Batch Code	CORRECT expiry date (please consider this)
3099120	WD00342A	2243AP0104	*2024 - 10*
3100780	WD00347A	5233AP0204	*2024 - 10*
3100780	WD00347A	3293AP0104	*2024 - 10*
3099120	WD00342A	3293AP0204	*2024 - 10*
3099120	WD00342A	2034AP0204	*2025 - 05*

2. Recommended Actions to Be Taken by the User

☒ Identify the product.

☒ Stop using the product

☒ Dispose off the product as per local requirements and based on SDS.

☒ Inform and provide evidence to your distributor, Olympus, that you have disposed of the products you had in your stock. A credit note for the product and disposal costs will be offered upon receipt of proof of disposal.

Catalogue Number	Olympus Code	Batch Code	CORRECT expiry date (please consider this)
3099120	WD00342A	2243AP0104	*2024 - 10*
3100780	WD00347A	5233AP0204	*2024 - 10*
3100780	WD00347A	3293AP0104	*2024 - 10*
3099120	WD00342A	3293AP0204	*2024 - 10*
3099120	WD00342A	2034AP0204	*2025 - 05*

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:	Reply form in Cover letter attached to this FSN
4.	6. Name/Signature	[redacted] Senior Regulatory Affairs Manager Ecolab Deutschland GmbH

		[redacted] Director Quality Health Care Europe Ecolab

	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. The Distributer shall inform and remind the end user at least 3 times which ensures the effectiveness of this corrective action towards the end customer of Olympus. 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.