Date: DD May 2023
Olympus reference: QIL FY24-EMEA-04-FY23-EMEA-12

URGENT FIELD SAFETY NOTICE

Return of certain Endoscopes for additional inspection
Attention: Endoscopy Department, Medical Engineering, Risk Management

Model Number	Brand Name	Serial numbers
<insert material number(s) of the affected product(s)> per customer	<insert material description of the affected product(s)>	<insert affected product serial number(s)> per customer

Dear Healthcare Professional:

Olympus' records indicate that the endoscope <type of endoscope, serial number xxx> was repaired in our facility on DD MM YYYY. The purpose of this communication is to inform you of an issue during the repair of your product and provide instructions on actions to be taken.

Olympus determined that after the repair of your endoscope, certain inspection tasks were not carried out. The missing inspection steps cover the following functionality: endoscope self-identification, radio-frequency identification (RFID), device labeling, and UDI labeling.

The risk associated with an incorrect or missing endoscope self-Identification function is a procedural delay (prolonged episode of care) due to switching to another endoscope. The risk associated with an incorrect RFID function is the potential for an insufficiently reprocessed device which could result in a contaminated device. This risk is limited to when ETD Premium is used and is not applicable if any other cleaning and disinfection method is used. For labeling and the UDI label, there is no direct patient impact identified. Olympus has not received any complaints from the market concerning this issue.

In an abundance of caution, Olympus recommends the return of your product for an additional inspection to ensure that your endoscope is meeting our repair and inspection standards.

Action steps to be taken by the end user:

1. Carefully read the content of this Field Safety Notice.
2. Inspect your inventory to identify the device(s) XXXXXXX with serial number(s) XXXXXXX.
3. If you have further distributed this product, identify your customers, and forward them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedback accordingly.
4. Indicate on the Reply Form that you have received and understood this Field Safety Notice by filling out and returning the completed enclosed Reply Form back to your local Olympus representative XXXXXXX latest by DD MM YYYY .
5. An Olympus representative will contact you to arrange a mutually convenient time for the return of your affected product for additional inspection. Additional inspection will be performed free of charge.

Your National Competent Authority has been informed of this Field Safety Notice.

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me at **[phone number]** or **[e-mail address].**

Sincerely,

REPLY FORM – QIL FY24-EMEA-04-FY23-EMEA-12

OLYMPUS URGENT FIELD SAFETY NOTICE **Recall of certain Endoscopes for additional inspection**
[Name & Address of Hospital/Medical Facility]
[Dept/Attn]
[**Date]**

I herewith acknowledge the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity of following the <insert product model number> Instructions for Use carefully.

Name (Signature) _____

Name (Print) _____

Position _____

Please send your completed paper form response to XXXXX mailto:latest by XXXX.