

S. Possidonio, August 7<sup>th</sup>, 2019

To:  
MERMAID MEDICAL A/S  
FRYDENBERGVEJ 25, 3660 STENLØSE  
DENMARK

**Subject: FSCA Notice**

Dear Valued Customer,

Company MEDAX – manufacturer of the medical device soft tissue semi-automatic biopsy needle BIO-FEATHER – is initiating a voluntary recall of the lot number indicated in the table below.

Product Code	Lot	Description
BF18100-00	02492-19	Semi-automatic biopsy needle BIO-FEATHER 18G x 100MM
BF18120-00	12078-18	Semi-automatic biopsy needle BIO-FEATHER 18G x 120MM

Our records show that your facility has purchased the affected lot.

**Important note:**

This notice must be transmitted to any structure where the potentially affected devices may have been transferred.

**Problem description:**

The coupling tooth of the device's sequential system may break during activation.

**Potential risk:**

Impossibility to perform the biopsy procedure and impossibility to expose the stylet to retrieve the sample.

**Medax Srl Unipersonale**

Headquarters: Via S. Pertini, 4 • 41039 • San Possidonio (MO) • Italy  
Company direct No. : +39 0535 1812757 • Fax No : +39 0535 1812744  
email: customercare@medax.it • PEC: medax@legalmail.it • www.medax.it

Registered Office: Via R. Piva, 1/A • 46025 • Poggio Rusco (MN) • Italy  
Vat N. /Fiscal Code N. Iscriz. Reg. Impr.: MN 02669860369 • N. REA: MN 233527, MO 403036 • Capitale Sociale Euro 100.011,00 i.v.

### Required Actions by Distributors and Users

- Please identify and quarantine any devices of the affected lot in your inventory.
- Provide a copy of this FSN and FSCA response form to all users/hospitals who may have received affected devices.
- Ask these users/hospital personnel to complete the FSCA response form and return to you.
- Confirm to Medax that you have completed the required activity for all of your impacted customers.

Upon receipt of the completed FSCA response form, MEDAX will contact you to arrange the return of the affected devices and the provision of replacement devices.

We inform you that the competent authorities were advised on this Field Safety Notice.

Medax places utmost importance to product quality and safety of our patients. We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused. If you have any question or concerns regarding this recall, please contact your MEDAX customer service team by email at:

[sales@medax.it](mailto:sales@medax.it)

[qa@medax.it](mailto:qa@medax.it)

[customercare@medax.it](mailto:customercare@medax.it)

We will remain at your entire disposal for any further information or clarifications you may require.

We thank you for your attention and cooperation

Best Regards

Stefano Cavalieri  
Quality Assurance  
Medax S.r.l. Unipersonale

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