



Annex 2 - letter from distributors to hospitals

San Giovanni in Persiceto, 07/05/2021

This letter contains important information that requires your immediate attention.

Dear Customer,

We, Adria Srl, are undertaking this Field Safety Corrective Action in relation to the lots listed in attachment 1 of this letter.

Explanation of the problem

Adria Srl is a manufacturer of class IIa and IIb medical devices.

The devices are marketed in sterile form, after having undergone an ethylene oxide sterilization process performed by the company Steril Milano Srl

Adria Srl received communication from the sterilizer about the falsification of the process parameters of the sterilization cycles.

So, we conducted a thorough investigation accompanied by sterility tests and residue eto, with positive feedback on the tested products.

As a precaution, we decide to recall the devices (listed in Annex 1) in stock at our distributors. With regard to hospitals and health services, the immediate quarantine and segregation of the same devices listed in Annex 1 present in the structure is required.

In attachment 1 you can find the extract of the affected lots.

Clinical impact

The use of non-sterile devices may lead to an increased risk of patient infection.

We would like to specify that Adria Srl has never been notified of adverse events or damage to patients potentially attributable to the problem covered by this report.

There are no specific follow-up actions for patients, where the product has already been used.

Actions required of hospitals and health facilities

1. Immediately discontinue use, identify and quarantine all items listed in Table A1 (list of products supplied), that are still present at your facility, that are new, unused, and still in their original packaging.

2. Fill in and sign the attached letter of Attachment 4 "Acknowledgment letter of Hospitals and Health facilities" specifying the quantity of the goods placed in quarantine, including their lot number, their code and inform your distributor and Adria Srl by sending an email to the following address: qa@adriamedical.com and export@adriamedical.com as soon as possible and in any case within 10 days of receipt of this letter.

3. Wait for information from your distributor and Adria Srl for the handling of the goods in question.

Corrective actions in place

Adria Srl is completing the qualification of a new OE sterilization service provider.



Contacts

For further information regarding this FSN please contact your distributor and Adria Srl at +39 347 2441014 or by email at the address ga@adriamedical.com or export@adriamedical.com

Adria Srl confirms that the relevant competent authorities have been notified of the actions described herein. Adria Srl would like to mean that the safety of its devices is a primary objective, and by issuing this FSN, Adria Srl wanted to maintain a prudent and collaborative approach, in order to manage the planned actions in the best possible way.

We apologize for any inconvenience this situation may cause and stay at your disposal for any clarification.

In faith

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