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 all biopsy needles.
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 qa@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

ADRIA srl
Società Unipersonale
Via Modena, 46
40017 S. GIOVANNI IN PERSICETO (BO) - Italy
Tel. +39 051 6810921 - Fax +39 051 6879188
E-mail: adria@adriamedical.com - www.adriamedical.com
Partita IVA. 02042571204

Table A1 - list of goods delivered to your facility

Code	Lot number	Quantity delivered

ADRIA Srl – Soc. Unipersonale
Headquarters: via Modena 46, 40017 San Giovanni in Persiceto (BO) - Italy
Warehouse and logistics: via San Francesco d'Assisi 15, 46020 Pegognaga (MN) - Italy
VAT Reg. Id. 02042571204 - Tel. +39 0376 559772
www.adriamedical.com- Email: customer-service@adriamedical.com
