



BELDICO SA

Rue André Feher, 3
Zoning de Aye
6900 Marche-en-Famenne
BELGIUM

Urgent Field Safety Notice

Commercial name of the affected product :

**Sterile disposable feeding bottles
Sterile disposable breast milk collector sets**

FSCA-identifier: AFMPS 21942

Beldico Complaint Reference: NC04545

Type of action : RECALL

Date : 11/02/2017

1. Details on affected devices

This "field safety notice" only applies to products with the article codes and lot numbers described in the attached list.

2. Description of the problem

Some Beldico EO sterile baby feeding bottles/breast milk collector sets for which quarantine period has not been fully completed have just been dispatched or delivered to some of our distributors.

These products cannot be used and have to be returned to the manufacturer Beldico as soon as possible.

3. Advise on action to be taken by the user

Please forward this mail to the concerned departments and services that use Beldico EO sterile baby feeding bottles/breast milk collector sets. Please control the batch numbers of these products you are using and if they are identical to the one listed here above, please stop using them and put them directly in quarantine.

Return the affected lots to your distributor, with possible exchange of products.

Please forward to Beldico the attached recall follow-up form duly completed.

4. Transmission of this Field Safety Notice

If you are a distributor, please forward this notice to your different customers/users.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.



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5. Contact reference person

For more information and/or questions regarding this recall, please contact Beldico sales department:

Customer Service
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Belgium
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We apologize for any inconvenience this may have caused and thank you for your cooperation and understanding.

Yours faithfully,

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Appendix 1: Product Recall form Beldico