Euromi S.A.
rue des Nouvelles Technologies, 11
B-4821 Andrimont, BELGIUM
T: +32 (0)87 29 22 21 | F: +32 (0)87 29 22 23
www.euromi.com

IMPORTANT
PRODUCTS RECALL

EUROMI reference : EN7-E-001-09052018

Andrimont, **May 9th, 2018**

Dear,

EUROMI S.A. initiates a voluntary recall of **N.L.F System® 1 & 2 products manufactured by EUROMI S.A..**

PRODUCTS CONCERNED BY THE RECALL:

PRODUCT REFERENCE	TRADENAME	BATCH NUMBER
1118HPF9412	N.L.F. System 1	18A15
		18A16
		18A17
		18A18
		18A19
1118HPF9433	N.L.F. System 2	18A12

RECALL REASON :

This action is started because of a change to the N.L.F System 1 & 2 that has not been successfully validated. This change requires additional validation to ensure patient safety.

A defect of the validation of the primary packaging is in question. This defect could have a consequence on the sterility of the product. In order to eliminate this risk, EUROMI S.A. has decided to carry out a batch recall.

EUROMI S.A. has determined that the product may be not sterile. The use of a non-sterile device in surgery can result in adverse health consequences, such as infection, which can put people's lives at risk and / or lead to death.

No reported adverse events associated with this change have been reported.

It is important that you keep EUROMI S.A. informed of any adverse effects or events associated with this device. Incidents can be reported by e-mail to **materiovigilance@euromi.com**.

INSTRUCTIONS :

We ask you to take the following measures as a matter of urgency:

- Read this notification carefully and make sure that the staff concerned knows the content.
- Immediately stop using the batches of products mentioned in this mail.
- Move to quarantine all affected products in your establishment.
- Complete and return the reply form attached to fax +32 (0) 87 29 22 23 or by email to **materiovigilance@euromi.com** even if the number of products concerned in your inventory is equal to zero.

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- The Customer Service will contact you to organize the return of the products.

CONTACT REFERENCE PERSON:

Mélanie KORDAS – EUROMI
rue des Nouvelles technologies, 11
B-4821 Andrimont, BELGIUM
T: +33 (0)3 27 837749

OTHER INFORMATION:

This notification has been communicated to all competent authorities and the notified body concerned, as required by the current regulations on medical devices.

We thank you in advance for your complete voluntary collaboration and please accept our apologies for the extra work involved.

Patient safety is our priority; we thank you in advance for your prompt intervention.

If you have any questions and / or comments regarding this letter, you can contact us via our e-mail at the following address: **materiovigilance@euromi.com**.
The teams of EUROMI S.A. remain at your disposal for any additional information related to this product recall.

Best regards,

Mélanie KORDAS
Vigilance manager

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So that EUROMI SA is assured of the good reception of the present mail, we thank you for completing and sending back this form by email **materiovigilance@euromi.com** or fax **+32 (0) 87 29 22 23**.
Upon receipt of this form, the company EUROMI S.A. will contact you to arrange the return of products.

Name and address of the establishment / Distributor	
Answer completed by:	
Function:	
Phone Number :	

Our inventory has been reviewed and the results are as follows:

☐ **We no longer have the relevant products in stock.**

☐ **We still have ...**

PRODUCT	BATCH NUMBER	QUANTITY

☐ We quarantined them and we want to return them.

☐ We confirm that we have received and taken note of this notification.

Date :

Signature :