



Quality contact :  **Denis Coakley 086 2551148**


Mail ref: 15 1986 «N_de_Chrono»CO/NU

Ecouen, 22th December, 2015

Subject : FSN-RECALL

Nutrisafe 2 feeding tubes code 363.062 batch 200715FE

Dear

We have identified a non-systematic manufacturing defect on **Nutrisafe 2 feeding tubes code 363.062 for specific lot 200715FE**. Some devices have the numbers printed on the tube in the wrong way. The markings should start from 5cm from the distal tip to the nutrisafe connection.

This defect may be visually detected.

We ask you to withdraw this batch.

We ask you to kindly acknowledge receipt of this letter, to complete and return the attached form by indicating involved quantities withdrawn from your institution.

The French health authorities (ANSM) have been informed of this FSN.

*For further information, you can directly contact **Mr Denis Coakley Managing Director**,
phone number **086 2551148** or email – **dcoakley@vygon.ie***

We apologize for any inconvenience this FSN-Recall may cause.

Christine OBER

Postmarket QA/RA Director

Service Qualité
Tél : 01.39.92.63.51
Fax : 01.39.92.64.82
E-mail : quality@vygon.com

Service Clients France
Tél : 01.39.92.63.81
Fax : 01.39.90.99.37
E-mail : commandes@vygon.com

Service Clients Export
Tél : 01.39.92.64.17
Fax : 01.34.29.19.34
E-mail : export@vygon.com





FSN-RECALL Nutrisafe 2 feeding tubes Code 363.062 lot 200715FE

ACKNOWLEDGMENT AND CUSTOMER RESPONSE FORM

Please complete and return this form:

by fax: 01 4105721 or e-mail to : fnoonan@vygon.ie & Copy dcoakley@vygon.ie

Name and address of the institution :

Full name of the person to contact:

Function :

☎ Phone number :

✉ E-mail :

We acknowledge receipt of the above FSN and that the information contained in this field safety notice has been shared with all recipients/ end users of above products within your organization.

Please tick the appropriate box :

You have Nutrisafe 2 feeding tubes code 363.062 Lot 200715FE : Yes No

✓ If you have units, number of units removed : _____

Signature and Date :

Service Qualité
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