



Børneafdeling 30  
Børne- og Ungdomsafdeling  
Nykøbing F. Sygehus  
Fjordvej 15  
4800 Nykøbing F.

Mail ref: 15 1986

Ecouen, 22<sup>th</sup> December, 2015

**Subject :** FSN-RECALL

**Nutrisafe 2 feeding tubes code 363.062 batch 200715FE**

Dear Madam, Sir,

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kindly acknowledge receipt of this letter, to complete and return the attached form by indicating involved quantities withdrawn from your institution.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 Jette Rubusch Sales- and Marketing Director phone number +45 21451010.*

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 : 01.39.90.29.37  
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**

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**Please complete and return this form:**

**e-mail to : [Jette.rubusch@vygon.dk](mailto:Jette.rubusch@vygon.dk)**

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**Name and address of the institution :**

**Børneafdeling 30  
Børne- og Ungdomsafdeling  
Nykøbing F. Sygehus  
Fjordvej 15  
4800 Nykøbing F.**

**Full name of the person to contact:** Helle Kjær

**Function : Nurse**

**Phone number : 56 51 50 30**

**E-mail : [hkj@regionsjaelland.dk](mailto:hkj@regionsjaelland.dk)**

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**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 : 25**

**Signature and Date :**

Service Qualité  
Tél : 01.39.92.63.51  
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E-mail : [quality@vygon.com](mailto:quality@vygon.com)

Service Clients France  
Tél : 01.39.92.63.81  
Fax : 01.39.90.29.37  
E-mail : [commandes@vygon.com](mailto:commandes@vygon.com)

Service Clients Export  
Tél : 01.39.92.64.17  
Fax : 01.34.29.19.34  
E-mail : [export@vygon.com](mailto:export@vygon.com)

