




«Nom\_de\_Etablissement\_»  
«Nom\_du\_correspondant»

«Adresse\_1»  
«Adresse\_2»  
«CP\_VILLE\_»

Quality contact : 

Mail ref: 18 0175 «N\_de\_Chrono»CO/NU

Ecouen, 12<sup>th</sup> February, 2018

**Subject :** URGENT: FSN-RECALL

**VYLIFE references 7506.02/03 and KIT VYLIFE references 5582.700/802/841/842/844**

Dear Sir, Madam,

We inform you that following the cessation of sale and the discontinuation of our routine maintenance program, we have initiated a recall of the devices references detailed below. All batches are to be recalled.

**VYLIFE references 7506.02/03 and KIT VYLIFE references 5582.700/802/841/842/844.**

**For this reason, we ask you to immediately withdraw these devices from services and to return them in-line with our instructions below.**

Please acknowledge receipt of this letter and complete and return the attached form after indicating the quantities withdrawn from your institution.

*The French health authority (ANSM) has been informed of this Field Safety Notice, FSN.*

For further information, should you require it, please contact your designated local market Vygon representative via telephone number detailed below:

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

Yours faithfully,

[Redacted signature area]

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





**URGENT: FSN-RECALL of all batches**  
**VYLIFE codes 7506.02/03 and KIT VYLIFE codes 5582.700/802/841/842/844**

**ACKNOWLEDGMENT AND CUSTOMER RESPONSE FORM**

Please complete and return this form by fax: **XXXXXXXXXX** or e-mail to : **XXXXXXXXXX**

<b>Name and address of the institution :</b>	
<b>Full name of the person to contact:</b>	«N_de_Chrono»CO/NU »  « TOWN_»
<b>Function :</b>	
<b>☎ Phone number :</b>	
<b>✉ E-mail :</b>	

**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 product listed below within your organisation.**

**Please tick the appropriate box:**

**You have VYLIFE/KIT VYLIFE:**

**Code 7506.02 :**  Yes  No If you have units, number of units removed, specify the batches: \_\_\_\_\_

**Code 7506.03 :**  Yes  No If you have units, number of units removed, specify the batches: \_\_\_\_\_

**Code 5582.700 :**  Yes  No If you have units, number of units removed, specify the batches: \_\_\_\_\_

**Code 5582.802 :**  Yes  No If you have units, number of units removed, specify the batches: \_\_\_\_\_

**Code 5582.841 :**  Yes  No If you have units, number of units removed, specify the batches: \_\_\_\_\_

**Code 5582.842 :**  Yes  No If you have units, number of units removed, specify the batches: \_\_\_\_\_

**Code 5582.844 :**  Yes  No If you have units, number of units removed, specify the batches: \_\_\_\_\_

**Signature and Date:**

\_\_\_\_\_  
 \_\_\_\_\_

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

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