




«Nom_de_Etablissement_»

«Nom_du_correspondant»

«Adresse_1»

«Adresse_2»

«CP_VILLE_»

Quality contact : 

Mail ref: 18 0175 «N_de_Chrono»CO/NU

Ecouen, 12th 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Please acknowledge receipt of this letter and complete and return the attached form after indicating the quantities withdrawn from your institution.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,

Christine OBER - Pharmacist

Postmarket Quality 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





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**

Name and address of the institution :	
Full name of the person to contact:	«N_de_Chrono»CO/NU » « TOWN_»
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 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
 Fax : 01.39.92.64.82
 E-mail : quality@vygon.com

Service Clients France
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 Fax : 01.39.90.29.37
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