



Quality contact : ☎ 0033 139 926 351
✉ nusur@vygon.com

Mail ref : 15 1475 «N_de_Chrono»CO/NU
Objet : FSN-RECALL
Y connector code 884.08

17th September, 2015

Dear Madam, Sir,

We have identified a non-systematic manufacturing defect on **Y connector code 884.08 for specific lots 021214EG, 100315EG, 090615EG, 170615EG and 270815EG.**

There is a possibility that the Y connector can be blocked and it is not visually detectable

We ask you to withdraw these batches.

A field safety notice has been sent end June 2015, for specific lots 021214EG and 100315EG.

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kindly acknowledge receipt of this letter, to complete and return the attached form by indicating involved quantities withdrawn from your institution.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 – VYCON IRELAND LIMITED, on phone number **086 2551148** or email – **dcoakley@vygon.ie***

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

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 : 01.39.90.99.37
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 Y connector CODE 884.08

ACKNOWLEDGMENT AND CUSTOMER RESPONSE FORM

Please complete and return this form:

by fax: 01 4105721 or e-mail to : dcoakley@vygon.ie and copy to fnoonan@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 Y connectors code 884.08

- | | | |
|--|--|---|
| <input checked="" type="checkbox"/> Lot 021214EG | <input type="checkbox"/> Yes <input type="checkbox"/> NO | If you have units, number of units removed: _____ |
| <input checked="" type="checkbox"/> Lot 100315EG | <input type="checkbox"/> Yes <input type="checkbox"/> NO | If you have units, number of units removed: _____ |
| <input checked="" type="checkbox"/> Lot 090615EG | <input type="checkbox"/> Yes <input type="checkbox"/> NO | If you have units, number of units removed: _____ |
| <input checked="" type="checkbox"/> Lot 170615EG | <input type="checkbox"/> Yes <input type="checkbox"/> NO | If you have units, number of units removed: _____ |
| <input checked="" type="checkbox"/> Lot 270815EG | <input type="checkbox"/> Yes <input type="checkbox"/> NO | If you have units, number of units removed: _____ |

Signature and Date :

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