

«Nom_de_l'établissement_»
«Nom_du_correspondant_de_matéριοvigilance»
«Adresse_1»
«Adresse_2»
«CP_VILLE»

Scé. Qualité : 
 @vygon.com

Ecouen, 26th November 2018

Nos réf : 18 0660 «N_de_Chrono» CO/NU

Objet : URGENT : FSN-Recall

DUALSTOP stoppers codes: 9888.00, 9888.001, 9888.002 and 9889.000

Dear Madam,Sir ,

We have identified a potential manufacturing defect on some **DUALSTOP stoppers codes 9888.00, 9888.001, 9888.002 and 9889.000 for specifics lots mentioned below.** This non-systematic defect can lead to a leakage.

DUALSTOP red stoppers:

code 9888.00 lots : 120617FD-160617FD-200917FD-250917FD-270917FD-061117FD-211117FD-301117FD-141217FD-090118FD-150118FD-310118FD-200218FD-080318FD-140318FD-260318FD-290318FD-110418FD-130418FD-260418FD-070518FD-180518FD-310518FD-050618FD-200718FD-300718FD-070918FD,

Code 9888.001 lots : 130917FD-161117FD-111217FD-190118FD-010318FD-140518FD-240518FD-130818FD,

DUALSTOP white stoppers code 9888.002 lots : 300517FD-081117FD-030118FD-250118FD-130218FD-190318FD-050418FD-180418FD-020518FD-090718FD-220818FD-300818FD,

DUALSTOP- blue stoppers code 9889.000 : lot 100718FD

For this reason, we ask you to immediately withdraw these batches 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Please acknowledge receipt of this letter and complete and return the attached form by indicating the quantities withdrawn from your institution.

The French health authorities (ANSM) have been informed of this Field Safety Notice, FSN.

For further information, should you require it, please contact your Vygon Quality contact, or sales administration via telephone number detailed below : xxxxxxxxxxxx.

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

Yours faithfully,

Christine OBER -

Postmarket QA/RA Director



Accueil
Tél : 01.39.92.63.63
Fax : 01.39.92.64.44
E-mail : questions@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
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Service Comptabilité
Clients - Tél : 01.39.92.63.65
Fournisseurs : Tél : 01.39.92.63.64
Fax : 01.39.92.64.44



URGENT : FSN-Recall

DUALSTOP stoppers codes: 9888.00, 9888.001, 9888.002 and 9889.000

ACKNOWLEDGMENT AND CUSTOMER RESPONSE FORM page 1/3

**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 above products within our organization.

Please tick the appropriate box:

You have DUALSTOP red stoppers :

- Code 9888.00 lot 120617FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 160617FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 200917FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 250917FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 270917FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 061117FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 211117FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 301117FD** Yes NO If you have units, number of units removed: _____



Accueil
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Adresse postale : 8 rue de Paris 95440 Ecouen - France

Siège social : 5 rue Adeline 95440 Ecouen - France

www.vygon.com



Value Life

URGENT : FSN-Recall DUALSTOP stoppers codes: 9888.00, 9888.001, 9888.002 and 9889.000

ACKNOWLEDGMENT AND CUSTOMER RESPONSE FORM page 2/3

- Code 9888.00 lot 141217FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 090118FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 150118FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 310118FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 200218FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 080318FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 140318FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 260318FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 290318FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 110418FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 130418FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 260418FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 070518FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 180518FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 310518FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 050618FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 200718FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 300718FD** Yes NO If you have units, number of units removed: _____
- Code 9888.00 lot 070918FD** Yes NO If you have units, number of units removed: _____
-
- Code 9888.001 lot 130917FD** Yes NO If you have units, number of units removed: _____
- Code 9888.001 lot 161117FD** Yes NO If you have units, number of units removed: _____
- Code 9888.001 lot 111217FD** Yes NO If you have units, number of units removed: _____



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Code 9888.001 lot 190118FD Yes NO If you have units, number of units removed: _____

Code 9888.001 lot 010318FD Yes NO If you have units, number of units removed: _____

Code 9888.001 lot 140518FD Yes NO If you have units, number of units removed: _____

Code 9888.001 lot 240518FD Yes NO If you have units, number of units removed: _____

Code 9888.001 lot 130818FD Yes NO If you have units, number of units removed: _____

You have DUALSTOP white stoppers :

Code 9888.002 lot 300517FD Yes NO If you have units, number of units removed: _____

Code 9888.002 lot 081117FD Yes NO If you have units, number of units removed: _____

Code 9888.002 lot 030118FD Yes NO If you have units, number of units removed: _____

Code 9888.002 lot 250118FD Yes NO If you have units, number of units removed: _____

Code 9888.002 lot 130218FD Yes NO If you have units, number of units removed: _____

Code 9888.002 lot 190318FD Yes NO If you have units, number of units removed: _____

Code 9888.002 lot 050418FD Yes NO If you have units, number of units removed: _____

Code 9888.002 lot 180418FD Yes NO If you have units, number of units removed: _____

Code 9888.002 lot 020518FD Yes NO If you have units, number of units removed: _____

Code 9888.002 lot 090718FD Yes NO If you have units, number of units removed: _____

Code 9888.002 lot 220818FD Yes NO If you have units, number of units removed: _____

Code 9888.002 lot 300818FD Yes NO If you have units, number of units removed: _____

You have DUALSTOP blue stoppers :

Code 9889.000 lot 100718FD Yes NO If you have units, number of units removed: _____

Signature et Date :



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