



( to be completed with your local contact addresses)

Date

Subject: **Product Recall - 2011-01-03 ALCOHOL PREP PADS & SWABSTICKS**

Dear valued Customer,

We have been informed by H&W Belgium, who subcontracts some of its production to Triad Group USA, about their decision to voluntary recall all lots of Alcohol Prep Pads and Swabsticks, both sterile and non-sterile. This recall has been initiated due to a customer concern on a potential contamination of the products with an objectionable organism that may or may not be related to the manufacture of these products. Attached you will find the Field Safety Notice from the TRIAD group.

All products are CE Medical devices class I, skin cleansing pads or sticks and meant to be used on the intact healthy skin prior to injection and could cause some rash or skin infection. Consequently we are recalling this product.

ART DESCRIPTION	VWR ART. REF.	Supplier	Supplier art ref.
<b>ALCO-PREP® ALCOHOL PADS 70% USP</b>	<b>HUARHW-0610H</b>	<b>H&amp;W</b>	<b>610H</b>
<b>ALCOHOL SWABSTICK NON-STERILE 70% USP</b>	<b>HUARHW-4300H</b>	<b>H&amp;W</b>	<b>4300H</b>
<b>ALCOHOL SWABSTICK</b>	<b>HUAR10-4300H_U</b>	<b>H&amp;W</b>	<b>10-4300H</b>
<b>ALCOHOL CLEANING SWAB</b>	<b>DELT192925</b>	<b>DELTALAB SL</b>	<b>192925</b>

We request you to check your stock and quarantine the products subject to this recall. In addition if you have further distributed this product, please identify your customers and notify them at once of this product recall.

To meet regulatory requirements, we would be grateful if you would confirm receipt of this recall letter by sending back the attached response form to **to VWR International asap, latest end of February 2011, even if you have no products subject to this recall. It will help us in our reporting to the European Surveillance Authorities on Medical Devices.**

VWR International will inform you on how to proceed with the quarantined products, as we depend on the instructions given by the manufacturer. Please **DO NOT RETURN THE GOODS in this stage of the recall process!**

( To be completed with the details of your sales organisation )



( to be completed with your local contact addresses)

Liability for any subsequent usage of the faulty batch will be entirely with yourselves.

Please accept our apologies for any inconvenience caused as a result of this occurrence and should any further assistance be required please do not hesitate to contact us.

Yours sincerely

( Contact details of a local responsible person)

( To be completed with the details of your sales organisation )

**FIELD SAFETY NOTICE**

Rubí, 31 January 2011



Dear customer,

The company H&W, BELGIUM, responsible for the product “**ALCOHOL PRED PADS**”, which subcontracts the production of it to the company TRIAD GROUP USA, informs us that this product has been voluntary recall. DELTALAB S.L.U is distributor of this product with code 192925.

Attached you will find the field safety notices from H&W and TRIAD, regarding this decision.

Enclosed you can find the list of products subject to this recall that we have supplied you since 2007:

BATCH	QUANTITY	SHIPPING DATE	DELIVERY NOTE
7A201	2000	05/09/2007	221602
	2000	25/10/2007	224828
	2000	15/11/2007	226131
	2000	21/11/2007	226570
	2000	21/01/2008	229777
	2000	24/01/2008	230124
	4000	07/02/2008	231183
	2000	13/02/2008	231628
	4000	05/06/2008	239003
	4000	17/07/2008	241862
8F201	4000	26/11/2008	249100
9G300	2000	22/04/2010	278948
	4000	30/07/2010	285880



TRIAD GROUP informs that this recall has been initiated due to a potential contamination of the product by *Bacillus cereus*. They have received a customer's claim and they have decided revalidate their production lines to ensure that they are not the source of these contamination issues.

Meanwhile they have decided, for prevention, recalling all products manufactured from 2007 until today.

We would be grateful if you could examine your inventory and quarantine product subject to the recall. In addition, if you have further distributed this product, please identify your customers and notify them at once of this product recall.

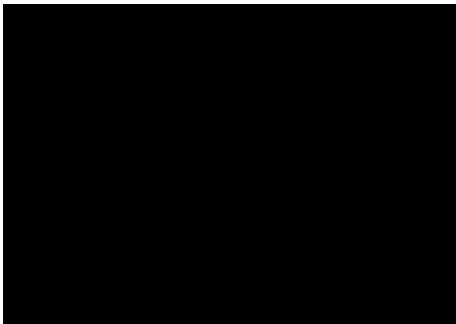
When you dispose of this information, we need that you provide us, as soon as possible.

With this required information and before returning the product recall, DELTALAB, S.L.U., will inform you how to proceed with the quarantine product, as we depends on the manufacturer instructions.

Please, do not hesitate to contact our Quality Department from DELTALAB, S.L.U. for further information.

This recall has been communicated to the Surveillance Unit of Medical Devices, which belongs to the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS).

Best regards,





Torenstraat 20  
B-3334 Glabbeek  
T +32(0)16 77 14 12  
F +32(0)16 77 12 40

info@h-w.be  
www.h-w.be  
BTW BE-0442.014.047  
RPR Leuven

Field Safety Notice

Glabbeek, 19.01.2011

Re: Triad Alcohol Prep Pads & Swabsticks Recall notice 1-3-11

Dear Madam, Sir,

We have been informed on January 13th 2011 by the Triad Group, USA, about their decision to voluntary recall all lots of Alcohol Prep Pads and Swabsticks, both sterile and non-sterile.

Attached you'll find two letters from Triad regarding this decision.

Triad Group is the sub-contractor of H&W cv in the manufacturing of Alco-Prep® and Alco-Swab®.

Both products are CE Medical Devices, Class I, non-sterile skin cleansing pads or sticks and meant, as you know, to be used on the intact healthy skin prior to injection. As you have noticed, both the H&W cv brands are not mentioned on the list (Facts: Alcohol Recall).

It is obvious that Triad's decision, which we are legitimately obliged to inform you about, puts us in a situation of "force majeure", caused beyond our reasonable control and occurring without our fault or negligence.

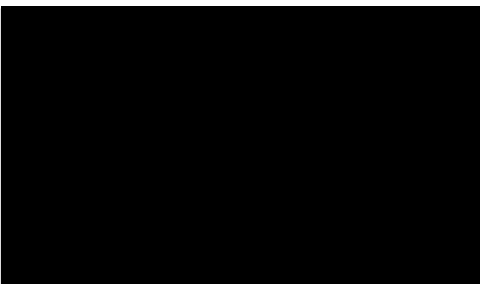
Consequently we are thus forced to recall the Alco-Prep® and Alco-Swab® product items produced since 2007. Our Customer Service Team will inform you about the practical execution.

The goods we currently have in stock of both product items (lot n° 0E300, 0G300, 0H300, 0K13, 0K25, 0K300, 0K301 and 0L06) have been put in quarantine awaiting further controls. We'll keep you informed in due course about the outcome.

Be assured that we do everything we can to secure the health of users and patients as well as the continuation of the supply of the said products.

Do not hesitate to contact us for further information.

Sincerely yours,







January 3, 2011

### URGENT DRUG RECALL

Dear Customer:

This is to inform you of a voluntary product recall involving **ALL LOTS** of ALCOHOL PREP PADS, ALCHOLOL SWABS, and ALCOHOL SWABSTICKS manufactured by Triad Group but which has been private labeled for many accounts. This recall involves those products marked as STERILE as well as non-sterile products.

This recall has been initiated due to concerns from a customer about potential contamination of the products with an objectionable organism that may or may not be related to Triad's manufacture of these products. We are, out of an abundance of caution, recalling these lots and revalidating our production lines to ensure that we are not the source of these contamination issues.

***Please immediately examine your inventory and quarantine product subject to the recall.*** In addition, if you have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification may be enhanced by including a copy of this recall notification letter. This recall should be carried out to the user or consumer level. Your assistance is appreciated and necessary to prevent potential patient harm.

Please complete and return the attached response form as soon as possible. **DO NOT RETURN THE PRODUCT ON YOUR OWN.** A return authorization number will be issued once the attached response form has been received. No product will be accepted for a return without a return authorization number. We will credit your account for the returned product and pay for the shipping costs to return to Triad. ***We ask that you fill out and return the response form even if you have no products subject to this recall, so it will help in our reporting to FDA.***

If you have any questions please call Triad Group Customer Service Monday through Friday between the hours of 8:30 A.M. and 4:00 P.M. Central Time: 262-538-2900 x2761 or e-mail at the following address: [recall.coordinator@triad-group.net](mailto:recall.coordinator@triad-group.net).

This recall is being conducted with the knowledge of the U.S. Food & Drug Administration.

Yours truly



700 West North Shore Drive      ▼      Hartland, WI 53029  
800.288.1288      ▼      262.538.2900      ▼      [info@triad-group.net](mailto:info@triad-group.net)



January 3, 2011

### Facts: Alcohol Recall

Thank you for visiting our recall information page. You may have received recent communication about a recall of alcohol wipes produced by Triad. There has been ONE report of a potential contaminant out of hundreds of millions of products sold. This situation is currently being investigated. As a precautionary measure Triad has voluntarily recalled all of our alcohol wipe products. If you have any of these products, please return it to the place of purchase for a full refund.

Symptoms: Possible rash or skin infection.  
If you are experiencing any of the above symptoms, please contact your physician immediately.

Brands affected:

Best Choice	Care One	CVS	Discount Drug Mart
Equaline	Equate	Exchange Select	Exact
Good Neighbor	Good Sense	Healthcare	Healthy Generations
Kroger	Leader	Life Brand	Longs
Major	MEIJER	Medicine Shoppe	Personelle
Publix	Premier Value	Quality Choice	Rite Aid
Reli-On	Remedy RX	Rexall	Safeway
Shoppers Drug	Sunmark	Up&Up	Top Care
Triad	Triad Sterile	Uniprix	Valu Plus
Western Family	Walgreens		

If you have further questions, please call (800) 288-1288

Yours truly,

The Triad Group, Inc.