

Address: 6090 Henri-Bourassa West, St-Laurent, QC H4R 3A6 CAN

Toll Free: 1.800.665.6334 | Fax: 514.338.1693

Website: www.medisca.com

08/14/2014

URGENT: TYPE II DRUG RECALL

Re: Chlorhexidine Gluconate Solution BP (20%), Lots: 56407/A, 56407/B and 56407/C

The supplier of Medisca's <u>Chlorhexidine Gluconate Solution BP (20%)</u>, <u>Lots: 56407/A, 56407/B and 56407/C</u> has issued a recall due to the product being contaminated with the bacteria Serratia Marcescens. To date, Medisca has not received any adverse event reaction notifications from customers, however as a precaution, Medisca has determined that the situation warrants a recall. Medisca has classified this recall as a **Type II**, defined in Health Canada policy POL-0160 as "a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote"

Please examine your stock <u>immediately</u> to determine if you have Lots <u>56407/A</u>, <u>56407/B</u> and <u>56407/C</u> on hand. If so, <u>discontinue dispensing the lot</u> and promptly return via post, to our Montreal Plant; ATTENTION: QS Department RETURNED GOODS, **Recall # R001**. Along with the parcel, please include the enclosed card by indicating the number of bottles being returned.

If you have further distributed any of the above lots, please contact your customers including patients immediately, advise them of the recall situation, and have them return their outstanding recalled stocks to you. Return these stocks as indicated above. A follow up will be made if you do not reply by August 21st, 2014.

You will be reimbursed by check or credit memo for the returned goods and postage, or, at your discretion, with replacement product. Should you have any questions regarding this recall, you may contact MEDISCA Pharmaceutique Inc. at 1.800.665.6334, from Monday to Friday, 8:00am to 7:00pm EST.

Health Canada has been advised of this recall and this letter serves an an official Recall Notification, Type II. Please return the enclosed card immediately providing the requested information, as well as any remaining stock.

We appreciate your assistance.

Regulatory Affairs Manager

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PLEASE FILL OUT AND RETURN IMMEDIATELY Return to 4509 Dobrin, Saint-Laurent, QC, H4R 2L8 1. We do not have any stock of Chlorhexidine Gluconate Solution BP (20%), Lots: 56407/A, 56407/B and 56407/C	
2. We are returning bottles of <u>Chlorhexidine Gluconate Solution BP (20%)</u> , Quantity of lot 56407/A Quantity of lot 56407/B Quantity of lot 56407/C	
Name of Responsible person: Signature:	
Company Name	
Address	
City	
ProvincePostal Code	