


Recolhimento de estoque de dispositivo médico Preservativo Blowtex Sensitive Super Aloe Vera

Caro cliente,

Descrição do problema	<p>Os lotes afetados de Preservativo Blowtex Sensitive Super Aloe Vera (código de fábrica: DF52U/N/AV/AI)) receberam um prazo de validade provisório com base no envelhecimento acelerado, ou seja, 180 dias a 50°C, de acordo com ISO4074:2015 e ASTM D3492:16.</p> <p>Um estudo de verificação em tempo real foi então iniciado conforme exigido pela ISO4074:2015 e ASTM D3492:16. Testes conduzidos no 3º ano passaram em todos os parâmetros confirmando uma vida útil de 3 anos; entretanto durante o teste no ano 4, as amostras de validação falharam nas propriedades de estouro. Portanto, com base no estudo de prazo de validade em tempo real, o prazo de validade desses preservativos será reduzido de 5 anos para 3 anos.</p>
Produtos envolvidos	<p>Preservativo Blowtex® Sensitive Super Aloe Vera</p> <p>2110050616; 2110060616; 2110070616; 2110480616; 2111020616; 2111070616; 2111080616; 2201020616; 2201030616; 2201140616; 2201150616; 2201970616; 2202050816; 2202060816; 2202500816; 2202510816; 2202690616; 2202700616; 2205930816</p>
Risco Envolvido	<p>O risco para o consumidor foi avaliado como muito baixo com base na seguinte lógica:</p> <ul style="list-style-type: none">• A distribuição foi interrompida no final de novembro de 2022• Com base na data de fabricação, as datas de vencimento revisadas seriam de setembro de 2024 a abril de 2025, sem nenhum produto colocado no mercado após dezembro de 2022• O tamanho médio da embalagem é de 3-9 unidades, que é consumido rapidamente pelo usuário final• O maior tamanho de embalagem é com 12 unidades, com data de validade revisada para set/24; nov/24; dez/24 ou jan/25.• Os dados de novos pedidos indicam uma rotação média de estoque de 90 dias. Portanto, espera-se que o estoque atualmente na prateleira seja vendido até março de 2023, com um vencimento mínimo revisado de setembro de 2024 até abril de 2025.• Espera-se que todos os produtos atualmente com usuários finais sejam consumidos antes das datas de vencimento revisadas• O estudo em tempo real de acordo com a exigência de ISO4074:2015 e ASTM D3492:16 confirmou uma vida útil de 3 anos e qualquer rotulagem futura do produto refletirá isso.
Ações a serem tomadas pelos clientes	<ol style="list-style-type: none">1. Se você recebeu algum desses lotes e ainda tem uma quantidade em estoque, recomendamos que devolva os lotes envolvidos para o detentor do registro. Endereço: ARMAZEM GERAL PROSEGUR - CNPJ 31.232.872/0001-09 IE 241.110.568.116; AV RIBEIRAO DOS CRISTAIS (G PRETO), 200 EMPRESARIAL PAINEIRA - CAJAMAR - SP.2. Se você recebeu esta comunicação diretamente da Blowtex, confirme o recebimento desta carta completando o formulário de resposta e o enviando através do e-mail comercial@blowtex.com.br ou 0800 773 6968. <p>Confirmar o recebimento desta notificação é de extrema importância para que a Blowtex possa continuar endereçando apropriadamente esse tema.</p> <ol style="list-style-type: none">3. Se você é um distribuidor de produtos da Blowtex, que comercializou produtos afetados, por favor notifique seus clientes a respeito deste recolhimento.
Mais informações e suporte	<p>Para dúvidas gerais sobre essa comunicação entre em contato com o Atendimento ao Cliente pelo 0800 773 6968 ou pelo e-mail comercial@blowtex.com.br.</p> <p>Horário de atendimento é das 9:00 às 12:30h e das 13:30 às 16:00h, exceto em feriados e finais de semana.</p>

Pedimos desculpas por qualquer inconveniente que essa ação de campo possa causar a você e a sua equipe.

Sinceramente,

DocuSigned by:

F29968822CC64ED
HELENA CRISTINA DE SOUZA
Representante Legal
Responsável Técnica
CRF - SP nº. 54.009

Anexo: Formulário de Resposta do Cliente



Fábrica de Artefatos de Látex Blowtex Ltda.

Escritório Comercial:
Rua Guararapes, 1.855 - 7º andar - Brooklin - São Paulo - SP
PABX (11) 3530-8200 / Fax: (11) 3530-8241
CNPJ.:59.548.214/0001-40
Insc. Est.:114.965.389.110
www.blowtex.com.br

FORMULÁRIO DE RESPOSTA AO CLIENTE

Nome da empresa:
Endereço:
Pessoa de contato:
E-mail:

Produto: Preservativo Blowtex Sensitive Super Aloe Vera

INSTRUÇÕES PARA PREENCHER O FORMULÁRIO:

Este formulário preenchido é necessário para fins de rastreamento. Marque as caixas aplicáveis abaixo. Sua assinatura e a data são obrigatórias.

- Eu acuso o recebimento desta carta
 Tenho o(s) produto(s) afetado(s) Quantidade (grosas) _____
 NÃO TENHO o(s) produto(s) afetado(s)

Nome (letra de forma): _____

Assinatura: _____ Data: _____ (DD/MM/AAAA)

Por favor, devolva o formulário preenchido por e-mail comercial@blowtex.com.br.

Certificado de Conclusão

Identificação de envelope: 5D408B10A73F489B81F1A2C3A3348145
 Assunto: Complete com a DocuSign: Comunicado Distribuidor Aloe_12.2022.docx
 Envelope fonte:
 Documentar páginas: 2 Assinaturas: 1
 Certificar páginas: 4 Rubrica: 0
 Assinatura guiada: Desativado
 Selo com Envelopeld (ID do envelope): Desativado
 Fuso horário: (UTC+10:00) Canberra, Melbourne, Sydney

Status: Concluído
 Remetente do envelope:
 Helena Souza
 Helena.Souza@lifestyles.com
 Endereço IP: 189.39.4.177

Rastreamento de registros

Status: Original Portador: Helena Souza Local: DocuSign
 10 de dezembro de 2022 | 09:02 Helena.Souza@lifestyles.com

Eventos do signatário

Helena Souza
 Helena.Souza@lifestyles.com
 Regulatory Affairs and Quality Assu. Sr. Manager
 LifeStyles Group
 Nível de segurança: E-mail, Autenticação da conta
 (Nenhuma)

Assinatura

DocuSigned by:

 F29968822CC64ED...

Adoção de assinatura: Estilo pré-selecionado
 Usando endereço IP: 189.39.4.177

Registro de hora e data

Enviado: 10 de dezembro de 2022 | 09:02
 Visualizado: 10 de dezembro de 2022 | 09:02
 Assinado: 10 de dezembro de 2022 | 09:03
 Assinatura de forma livre

Termos de Assinatura e Registro Eletrônico:

Aceito: 16 de janeiro de 2020 | 06:12
 ID: a9e2ec4d-9a49-4902-be5c-95b520c46321

Eventos do signatário presencial	Assinatura	Registro de hora e data
Eventos de entrega do editor	Status	Registro de hora e data
Evento de entrega do agente	Status	Registro de hora e data
Eventos de entrega intermediários	Status	Registro de hora e data
Eventos de entrega certificados	Status	Registro de hora e data
Eventos de cópia	Status	Registro de hora e data
Eventos com testemunhas	Assinatura	Registro de hora e data
Eventos do tabelião	Assinatura	Registro de hora e data
Eventos de resumo do envelope	Status	Carimbo de data/hora
Envelope enviado	Com hash/criptografado	10 de dezembro de 2022 09:02
Entrega certificada	Segurança verificada	10 de dezembro de 2022 09:02
Assinatura concluída	Segurança verificada	10 de dezembro de 2022 09:03
Concluído	Segurança verificada	10 de dezembro de 2022 09:03
Eventos de pagamento	Status	Carimbo de data/hora
Termos de Assinatura e Registro Eletrônico		

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- ii. send us an e-mail to diana.lew@lifestyles.com and in the body of such request you must state your e-mail, full name, US Postal Address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

Required hardware and software

Operating Systems:	Windows® 2000, Windows® XP, Windows Vista®; Mac OS® X
Browsers:	Final release versions of Internet Explorer® 6.0 or above (Windows only); Mozilla Firefox 2.0 or above (Windows and Mac); Safari™ 3.0 or above (Mac only)
PDF Reader:	Acrobat® or similar software may be required to view and print PDF files
Screen Resolution:	800 x 600 minimum

Enabled Security Settings:	Allow per session cookies
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