

Recolhimento de estoque de dispositivo médico

Preservativo Blowtex Zero

Caro cliente,

Descrição do problema	Os lotes afetados de Preservativo Blowtex Zero (código de fábrica: SS52MU/N/SL/00) 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. Um estudo de verificação em tempo real foi então iniciado conforme exigido pela ISO4074:2015 e ASTM D3492:16. 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.
Produtos envolvidos	Preservativo Blowtex Zero Lotes: 2106011116; 2105130816; 2106781116; 2106041116; 2108031016; 2108591016; 2108071016; 2108081016; 2111051016; 2112681016; 2112080516; 2112080416; 2112090516; 2112380416; 2112091016; 2112070516; 2112830516; 2201060416; 2112060416; 2112080716; 2112800516; 2112341016; 2201651016; 2201050516; 2201980516; 2202011016; 2202021016; 2202030516; 2201160516; 2202040516; 2202050916; 2202051016; 2202060516; 2202080516; 2202100516; 2202080916; 2207020516; 2207742716;
Risco Envolvido	O risco para o consumidor foi avaliado como muito baixo com base na seguinte lógica: • A distribuição foi interrompida no final de novembro de 2022 • Com base na data de fabricação, as datas de vencimento revisadas seriam de abril de 2024 a junho de 2025, sem nenhum produto colocado no mercado após dezembro de 2022 • O tamanho médio da embalagem é de 3-6, que é consumido rapidamente pelo usuário final • O maior tamanho de embalagem é 16, com data de validade revisada para dezembro de 2024. O próximo maior é um pacote com 12, com validade revisada para novembro de 2024 e janeiro de 2025 • 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 abril de 2024 até junho 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	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 email comercial@blowtex.com.br ou 0800 773 6968. Confirmar o recebimento desta notificação é de extrema importância para que a Blowtex possa continuar endereçando apropriadamente esse tema. 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	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. Horário de atendimento é das 9:00 às 12:30h e das 13:30 às 16:00h, exceto em feriados e finais de semana.

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

Sinceramente,

DocuSigned by:

Helena Souza

E29968822CC64ED...

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 Zero

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: 3B1E54C15226492485FE8C6789855FB4
 Assunto: Complete com a DocuSign: Comunicado Distribuidor_V2.pdf
 Envelope fonte:
 Documentar páginas: 2
 Assinar páginas: 4
 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: 189.46.94.228

Rastreamento de registros

Status: Original
 10 de dezembro de 2022 | 03:20

Portador: Helena Souza
 Helena.Souza@lifestyles.com

Local: DocuSign

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: 189.46.94.228

Registro de hora e data

Enviado: 10 de dezembro de 2022 | 03:20
 Visualizado: 10 de dezembro de 2022 | 03:21
 Assinado: 10 de dezembro de 2022 | 03:21
 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 03:20
Entrega certificada	Segurança verificada	10 de dezembro de 2022 03:21
Assinatura concluída	Segurança verificada	10 de dezembro de 2022 03:21
Concluído	Segurança verificada	10 de dezembro de 2022 03:21
Eventos de pagamento	Status	Carimbo de data/hora
Termos de Assinatura e Registro Eletrônico		

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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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