

CARWILD CORPORATION
3 STATE PIER ROAD
NEW LONDON, CT 06320
USA

Phone: 1-860-442-4914
Fax: 1-860-442-5895

10/16/2024

MEDEX INSTRUMENTATION SERVICE

Markerkant 10-136e Postbus 1230
1316 AL Almere 1300 BE Almere
Netherlands Netherlands
l.mulder@medex-instrumenten.com;
k.timmerman@medex-instrumenten.com

ON BEHALF OF FIRST AID BANDAGE COMPANY (FABCO)

RECALL NOTICE
URGENT

PLEASE READ EACH QUESTION CAREFULLY. PLEASE CHECK WITH ALL COMPANY REPRESENTATIVES WHO MAY HAVE RECEIVED OR USED THIS PRODUCT BEFORE ANSWERING. RECHECK THE ANSWERS YOU HAVE WRITTEN PRIOR TO MAILING.

CARWILD CORPORATION HAS DECLARED A RECALL OF THE
FOLLOWING PRODUCT:

CEASE FURTHER DISTRIBUTION OR USE OF ANY REMAINING PRODUCT IMMEDIATELY	
PRODUCT DESCRIPTION	FABCO IVALON EYE WICKS, CELLULOSE SURGICAL SPEARS AND ANATOMICAL NASAL PACK WITH TUBE.
PRODUCT PART NUMBER(S)	Q770410 – 24F1638 (13 Dispensers)
PRODUCT LOT NUMBER(S)	See above.

REASON FOR RECALL	During post-sterile Tyvek pouch burst testing, some samples tested fell below the approved limits; package seal is out of specification and the sterile barrier cannot be guaranteed for the life of the product.

RECALL INSTRUCTIONS:

	QUESTION	YES	NO	COMMENT
1	Did your firm receive shipment of the product being recalled? If NO, please SKIP the remaining questions; sign last page and return.			
2	Do you currently have any of the recalled products on hand? Please check inventories before answering.			
3	If the answer to Question 2 is 'YES,' please contact Carwild to coordinate the return the product to Carwild Corporation?			
4	If the answer to Question 2 is 'NO,' do you plan to contact all locations /customers that your company has distributed this product to? Distributors are responsible to notify all your customers who may have received this product.			
5	Have you received any reports of illness or injury related to this product? Please provide copies of reports or attach report details.			
6	Can you provide traceability for the location of all of this product shipped to your company?			

	Please provide shipment history (quantities and locations shipped)			
7	Please provide any additional details relevant to this product /product issue.			

Name of person completing questionnaire:

Print Name: Karin Timmerman

Title: Director

Company: Medex Instrumenten Service

Sign Name:

Date: 23-10-2024

SEND RECALL RESPONSE BY ONE OF THESE METHODS:

METHOD	REFERENCE	DETAILS
MAIL	On Envelope: ATTENTION: PRODUCT RECALL RESPONSE	CARWILD CORPORATION 3 STATE PIER ROAD NEW LONDON, CT 06320 USA
E-MAIL	Subject Line: PRODUCT RECALL RESPONSE	regulatory@carwild.net and customerservice@carwild.net
FAX	Fax Coversheet Subject: PRODUCT RECALL RESPONSE	1-860-442-5895

TELEPHONE (Voice)	Call for questions or additional information. Please introduce as inquiry related to RECALL NOTICE	Regulatory 1-860-442-4914 x111 Customer Service 1-860-442-4914 x110
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NOTE:

*PLEASE RESPOND WITHIN 30 DAYS OF THE RECEIPT OF THIS RECALL NOTICE.
IF NO RESPONSE HAS BEEN PROVIDED WITHIN 30 DAYS, EXPECT FOLLOW UP
COMMUNICATIONS RELATED TO THIS MATTER.
TIMELY RESPONSE AND COOPERATION IS GREATLY APPRECIATED.*