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FAX COVER

From: *NDC Homecare dba Preferred Medical* *Djana Milliken – Compliance* ***URGENT*** ****This is being faxed/emailed to the "bill to" account for your company. Please distribute to any/all branches.******	
To: *Purchasing or Regulations Department*	**Date:** *1/23/2019*
Pages: *3* *(Including cover page)*	
Regarding: *Urgent Medical Device Recall Notification* *Teleflex - Rusch Drainage Bags* *Item # 390000 & 390060*	

Comments:

Dear Distributor,

Attached is a letter we received from Teleflex regarding the recall on the Rusch Drainage Bags. Our records indicate that you purchased this product from us. Please read attached letter and check your inventory for any affected product with listed lot number. If you have any of this product in stock please fill out attached "Request for return" form, so that we can issue you a RGA for return. ***Also, please make note that no credit will be issued without an RGA. If you have any questions please feel free to contact me. It is very important that we receive a response, a record of receipt is very important in documentation of these types of notices.*** *Additionally, if you have distributed these products to your customers, please advise them of the recall, and have return any affected product to you.*

Thanks,

Djana Milliken

Djana Milliken

407 New Sanford Road, La Vergne, TN 37086
compliance@ndc-inc.com / Phone: 615-324-6375 / Fax: 615-229-6801

Urgent Medical Device Recall Notification

Rüsch® Drainage Bags

EIF-000308

[Date]

To: Risk Manager

Teleflex has voluntarily issued a recall for the following product:

Product Name	Product Code	Lot/Batch Number	GTIN
Rüsch® Premium Drain Bag	390000	20161005 20170701 20161120 20170801 20161125 20170902 20170105 20170904 20170210 20171001 20170301 20171101 20170401 20171201 20170402 20180101 20170501 20170802 20170601	14026704645708
Rüsch® Urinary Drainage Bag	390060	20161005 20170701 20161120 20170801 20161125 20170901 20170105 20170902 20170210 20170903 20170401 20170904 20170402 20171101 20170501	14026704645715

Teleflex is voluntarily recalling these products because the device labels are not UDI compliant. The missing UDI compliance information on the labeling would not affect the function/performance of the device itself. Other label information and warnings are unaffected by this labeling.

No patient injury has been reported.

Product code and lot combinations not referenced above are not impacted by this field action.

Our records indicate you have received products that are subject to this recall. We are notifying our customers to take the following actions:

1. Immediately discontinue use and quarantine any products with the product codes and lot numbers listed above.
2. Complete the enclosed Recall Acknowledgement Form and fax to **[distributor fax number]**.
3. Once the fax is received, we will provide instructions on how to return any affected product directly to **[distributor name]**.
4. If you have no affected stock, please complete the enclosed Recall Acknowledgment Form and fax it to **[distributor fax number]**. This will allow us to document your receipt of this letter.

The U.S. Food and Drug Administration has been notified of this action.

We apologize for any inconvenience this action may cause you or your patients, and remain committed to providing high quality, safe and effective products.

Sincerely,

[Distributor Representative]

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1/23/2019

Teleflex - Rusch Drainage Bags

Please fill out and fax/email this distributor form within 10 business days, even if you do not have the recalled product.

Please complete and fax to: 615-229-6801 or email to: compliance@ndc-inc.com

REQUEST FOR RETURN FORM

Customer Information

Account No. _____

Account Name _____

Address _____

City/State/Zip _____

Contact Name _____

Phone No. _____

Fax No. _____

Email _____

Inventory Information

Item number	Lot number	Quantity to return
390000		
390060		

☐ I have read and understood the information within the accompanying notification. All relevant customers/ personnel have been informed of its contents, any necessary actions taken and records retained as part of our documentation.

☐ We have inspected our inventory and have no product related to this recall

_____

Completed by: (Print Name /Signature/Date)

Returned Completed form to:

Djana Milliken
Fax #: 615.229-6801
Email: compliance@ndc-inc.com