Johnson & Johnson
CONSUMER INC.

URGENT: MEDICAL DEVICE RECALL

20th Dec 2017

Dear Retailers,

This is to inform you of a voluntary product recall involving the following:

Product Name	UPC	Case Code	Outer Case GTIN
COACH® Self-Adhering Sports Wrap	381370079286	100497502	003813700497530024
	381370079293	100497602	003813700497600024
BAND-AID® Brand First Aid Products SECURE-FLEX® Wrap	381371161515	111615100	103813711615120000
	381371161508	111615000	103813711615050000
BAND-AID® Brand First Aid Products HURT-FREE® Wrap	381371161454	111614500	10381371161451
	381371161461	111614600	103813711614680000

Johnson & Johnson Consumer Inc. is initiating a voluntary, Class II recall at the retail level in the U.S. of select COACH® Self-Adhering Sports Wraps, BAND-AID® Brand First Aid Products SECURE-FLEX® Wraps and BAND-AID® Brand First Aid Products HURT-FREE® Wraps products. The current labeling claim states "not made with natural rubber latex" which needs to be updated based upon recent awareness that natural latex was used as a base ingredient in the early-stage manufacturing process, which reduces the allergic protein found in natural latex. A review of the available information reveals that the overall risk to patients and consumers is remote for potential non-serious allergic reactions and unlikely for serious allergic reactions. This may cause higher use and underreporting of allergies in consumers with preexisting rubber and/or latex allergies.

The impacted UPCs under this recall have the claim "not made with natural rubber latex" on the package. Examples of the packaging for each product is attached with the claim circled in red. This product was shipped from November 1, 2015 – November 1, 2017.

Action Requested:

1. Immediately examine your inventory and quarantine the above-mentioned product subject to recall.
2. Please complete the enclosed Business Reply Form and return immediately the form by emailing to BandAid8687@stericycle.com or faxing to (1-888-965-5802).
3. If you have any questions regarding the form, please call Stericycle at (1-855-215-5023).

Please return ALL inventory of the identified product above. No product other than that specified is to be returned.

This recall should be carried out to the retail level.

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We appreciate your cooperation in helping us successfully execute this voluntary recall. Please complete and return the enclosed response form as soon as possible. If you have any questions regarding the return of these products, please call Stericycle at (1-855-215-5023). If you have any questions about the product, please contact your Johnson & Johnson Consumer Inc. Sales Representative.

This recall is being made with the knowledge of the U. S. Food and Drug Administration

Derek Henderson
Sr. Director, North America Regional Quality & Compliance
Johnson & Johnson Consumer Inc.

Enclosures:
Business Reply Form

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COACH® Self-Adhering Sports Wrap	381370079286	100497502	00381370049753024
	381370079293	100497602	00381370049760024

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	381371161508	111615000	103813711615050000

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Product Name	UPC	Case Code	Outer Case GTIN
BAND-AID® Brand First Aid Products HURT-FREE® Wrap	381371161454	111614500	10381371161451
	381371161461	111614600	103813711614680000