

Fresenius Kabi Canada Ltd.

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April 20, 2020

CONFIDENTIAL

SUBJECT: New products and code consolidation for Transfer Packs

Dear Valued Customer,

This is to notify the customer that Fresenius Kabi Canada has reviewed the portfolio of Transfer Packs and will be adding new product offerings, while also shifting some existing device identifiers to new device identifiers, as per lists below, throughout 2020:

New Device Identifier	Description	
R6R2031	TRANSFER PACK CONTAINER WITH COUPLER	
	LABELED AS	
	COMPOFLEX 1F – EMPTY – 1000 COUPLER	

Table 1: New Products added to Transfer Pack Portfoliofor Class II Medical Device License No. 10005:

Please refer to the Directions/Instructions for Use for warnings and precautions associated with the listed products.

Table 2: New Device Identifiers in Transfer Pack Portfolio.Conversion of current device identifiers to new device identifiers will becompleted by end of 2020 for Class II Medical Device License No. 10005.

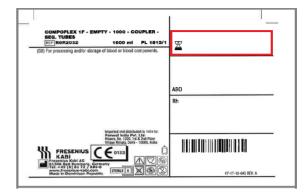
Current Device Identifier	Current Description	New Device Identifier	New Description
4R2014	TRANSFER PACK CONTAINER WITH COUPLER, 300 ML	R6R2074	COMPOFLEX 1F - EMPTY - 400 - COUPLER
4R2001	TRANSFER PACK CONTAINER WITH COUPLER, 150 ML	R6R2001*	COMPOFLEX 1F- EMPTY-150-COUPLER- SEG. TUBE
4R2004	QUADRUPLE TRANSFER PACK CONTAINER WITH COUPLER, 150 ML	R6R2004*	COMPOFLEX 4F EMPTY - 150/150/150/150 – COUPLER - SEG: TUBES
4R2023	TRANSFER PACK CONTAINER WITH COUPLER, 600 ML	R6R2023*	COMPOFLEX 1F - EMPTY - 600 - COUPLER - SEG. TUBE
4R2024	TRANSFER PACK CONTAINER WITH NEEDLE ADAPTER, 600 ML	R6R2024*	COMPOFLEX 1F - EMPTY - 600 - LUER MALE - SEG. TUBES
4R2027	TRANSFER PACK CONTAINER WITH 8 COUPLERS, 600 ML	R6R2027*	COMPOFLEX 1F - EMPTY - 600 - 8 COUPLERS
4R2032	TRANSFER PACK CONTAINER WITH COUPLER, 1000 ML	R6R2031	COMPOFLEX 1F - EMPTY - 1000 - COUPLER
R4R2041	TRANSFER PACK CONTAINER, 2000 ML	R6R2041*	COMPOFLEX 1F – EMPTY – 2000 – COUPLER – SEG. TUBES

(*) Products are identical (e.g.: 4R2004 = R6R2004) except for a new product code (device identifier) and a new product description.

Please refer to the Directions/Instructions for Use for warnings and precautions associated with the listed products.

All products listed above include:

- Dust covers (individual packaging)
- 3-year shelf life, as of manufacturing date
- Expiry date included on the product label (see image)



Expiry date symbol and location on product label

Over time, this information may be subject to change based on regulations, standards and guidance.

Please contact your local representative, Customer Service at 1-877-821-7724 or either of the signees below for any questions.

Sincerely,

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