



June 8, 2009

Dear Valued Customer,

The purpose of this communication is to provide information. No action is required.

Kimberly-Clark Health Care (KCHC) recently provided the Food and Drug Administration (FDA) updated data on the KIMGUARD Sterilization Wrap product lines. The most recent FDA Draft Guidance for sterilization packaging was used to determine the testing methodologies.<sup>1</sup>

Rest assured there have been no changes to the KIMGUARD product lines in over five years, just the testing methodologies. And at no time has the FDA required KCHC to stop marketing or selling the KIMGUARD product lines

KCHC has received updated 510(k) clearances to market the KIMGUARD One-Step\* product line (K082177) and the KIMGUARD Sterilization Wrap product line (K082554).

The FDA now requires Directions for Use to be included in each case of KIMGUARD product. Until customers receive the Directions for Use in the cases, the product they are purchasing was cleared under the previous 510(k) (K881471). KCHC expects the product with Directions for Use to be delivered to customers in the fall of 2009.

The Kimberly-Clark sales force will in-service each customer regarding the contents of the Directions for Use prior to implementation. At this time, there is no reason to change current practices and protocols.

Kimberly-Clark is committed to providing safe, effective products for our customers, and we are confident in the quality of our KIMGUARD Sterilization Wrap products.

If you have questions or would like to discuss further, please call your Kimberly-Clark Sales Representative, or 1-800-742-1996.

Regards,

Jay Hexamer  
General Manager, North America Sales and Marketing  
Medical Supplies

<sup>1</sup> "Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA"  
(<http://www.fda.gov/cdrh/ode/guidance/1388.pdf>)