



June 2, 2025

To Whom It May Concern:

In accordance with the U.S. Department of Health and Human Services Food and Drug Administration's *Guidance for Industry and Food and Drug Administration Staff Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not made with Natural Rubber Latex*, issued on: December 2, 2014, Kirwan Surgical Products LLC hereby certifies that the products we manufacture, including their packaging, are:

***NOT MADE WITH NATURAL RUBBER LATEX***

If you require additional information, please feel free to contact us toll-free at 1 (888) 547-9267 and/or consult the following FDA hyperlink: <https://www.fda.gov/media/85473/download>.

Sincerely,

A handwritten signature in blue ink, appearing to read "Matthew R. Prario", is written over a blue horizontal line.

Matthew R. Prario  
Regulatory Affairs Manager

