



January 1, 2010

Ref: **FDA Compliance of**
PolyWear™ Personal Protection Gowns and
VR™ Protective Wear Gowns

To Whom It May Concern:

PolyConversions, Incorporated manufactures and markets disposable personal protection gowns under FDA 510(k) pre-market authorization number K925077.

In compliance with FDA requirements, PolyConversions has tested their *PolyWear™* Personal Protection Gowns by an independent laboratory in accordance with ASTM Standards. These tests included: Breaking Load, Tensile Strength, Elongation at Break, and Penetration Resistance to Synthetic Blood.

Under the FDA authorization, these personal protection gowns are intended To be used as disposable personal protection (apparel) equipment in compliance with the OSHA Bloodborne Pathogen Standard, 29 CFR Part 1910.1030. As required under this Standard, these gowns, when properly used, do not permit blood or potentially infectious materials to pass through to, or reach the employee's work, street clothes, or skin (under normal conditions) for the duration of the time which the protective gowns will be used.

Sincerely,

William B. Smith
Vice President