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To Whom It May Concern:

The response to questions about gluten content in Restore™ gloves and information for people following a gluten-free diet are described below, to the best of my knowledge.

Topical application of gluten is not considered to be a route of exposure for people with celiac disease. The peptides generated by the digestion of gluten trigger the immune response that causes celiac disease only after gluten *is ingested*. The primary concern for topical use of gluten-containing products is that products applied to the hands, or by the hands, may be inadvertently ingested if proper hand-washing procedures are not followed prior to eating.

The oats¹ used in the Restore™ oatmeal coating were tested for the presence of gluten and I reviewed the results of such testing. Such gloves were found to contain gluten above the FDA threshold for labeling of a food product or ingredient as gluten-free²; however, based on the manufacturing process, each glove would end up by containing less than 1 microgram of gluten, which is well below the tolerable daily intake level identified by the FDA³. Research has in fact shown that in order to be potentially harmful for even the most sensitive celiac patients, gluten would have to be *ingested* in amounts of at least 0.015 mg per day, i.e. more than 15 times the amount of gluten present in a whole glove.

Thus, it is safe to conclude that the Restore™ glove's oatmeal-coated surface contains such a minimal amount of gluten that glove use cannot be expected to impact celiac individuals following a gluten-free diet.

A handwritten signature in blue ink that reads "Stefano Guandalini". The signature is fluid and cursive.

Stefano Guandalini, MD

¹ Oats are naturally gluten-free; however, oats may contain gluten due to contamination from other grains due to crop rotation practices and shared equipment use during harvesting and processing of the grains.

² FDA has set a gluten limit of less than 20 parts per million (ppm) for foods that carry the label "gluten-free," "no gluten," "free of gluten," or "without gluten."

³ In *Health Hazard Assessment for Gluten Exposure in Individuals with Celiac Disease: Determination of Tolerable Daily Intake Levels and Levels of Concern for Gluten* (Office of Food Safety. Center of Food Safety and Applied Nutrition. Food and Drug Administration. May 2011.), the FDA concludes that "the tolerable daily intake level for gluten in individuals with CD was determined in a safety assessment to be 0.4 mg gluten/day for adverse morphological effects and 0.015 mg gluten/day for adverse clinical effects."