Clinton County Industrial Park P. O. Box 270, North Road McElhattan, PA 17748 (570)769-6900 (570)769-4201 Fax



Vemo

Date: 8/5/15

To: Whom it may concern

From: Dana Walker

Re: General FQP product safety statement

First Quality Products manufactures finished goods in compliance with the requirements outlined in FDA QSR/GMP for Class 1, Exempt devices. First Quality Products, Inc. is currently registered and has listed each of its medical devices with the Food and Drug Administration as specified under 21 CFR Part 807. Registration Number: 2529604

FQP products are medical devices regulated by the Food and Drug Administration (FDA) federal agency and not under jurisdiction of the Consumer Products Safety Commission (CPSC) and the scope of the Consumer Products Safety Improvement Act of 2008.

First Quality Products is also self-certified in conformance to the use of the CE Marking as provided in the EC Directive 93/42/EEC for Class 1 Products (non measuring function).

Medical devices manufactured by First Quality Products, Inc. for the management of incontinence have been assessed for safety and potential health hazards. These evaluations have been conducted by an independent third party reviewer competent to provide an adequate assessment.

Independent review has confirmed that FQP incontinence devices are safe for their intended use and pose no health hazards to humans.

Products manufactured by FQP do not require a Material Safety Data Sheet (MSDS) to be supplied to purchasers of the products. Components of First Quality Products incontinence management products may include:

Polyethylene or polypropylene films and fabrics Block polymer construction adhesives Wood pulp (All are ECF – Elemental Chlorine Free bleaching) Polymeric substitutes for latex (FQP products contain no natural latex) Polyacrylate superabsorbents Silicone release papers

Further information can be obtained by calling 570-769-4279.

Dana Walker Quality Assurance Manager