

CERTIFICATIONS

ISO 9001:2008 International Standards Organization, Quality Management System

FDA 21 CFR 820 Quality System Regulation cGMP Compliant

FDA 21 CFR 175.105 Adhesives

FDA 21 CFR 175.125 Pressure-Sensitive Adhesives

FDA 21 CFR 177.2600 Rubber Articles Intended For Repeated Use

FDA 21 CFR 177.1550 Plastic Articles Intended For Repeated Use

FDA 21 CFR 186 Indirect Food Additives Affirmed As Generally Recognized As Safe (GRAS)

USDA FSIS (Food Safety and Inspection Service) per FDA 21 CFR 7.12 and 21 CFR 7.13

3-A Sanitary Standards 18—as Amended, For Multiple-Use Rubber and Rubber-Like Materials Used As Product Contact Surfaces in Dairy Equipment

3-A Sanitary Standards 20—as Amended, For Multiple-Use Plastic Materials Used As Product Contact Surfaces in Dairy Equipment

3-A Sanitary Standards 84—as Amended, Personnel Access Ports for Wet Applications

US Pharmacopeia Class VI,

USP 27, NF 22, <88> Biological Reactivity Tests, *In Vivo*

US Pharmacopeia MEM Elution Cytotoxicity,

USP 27, NF 22, <87> Biological Reactivity Tests, *In Vitro*

US Pharmacopeia Elastomeric Closures for Injection, Purified Water and IPA Extract,

USP 29, NF 24, <381> Elastomeric Closures for Injections

European Pharmacopeia Compliant

AH/TSE Free™, Animal and Human Derived Ingredients Free

RoHS, Restrictive Substances, European

RoHS, Restrictive Substances, China

Quality Gaskets and Gasket Materials from Quality People™