

Top Quality Manufacturing, LLC

Comprehensive Internal Compliance Program and Declaration

INTRODUCTION

Top Quality Manufacturing, LLC (The “Company”) is committed to high standards of ethical conduct and corporate compliance. To that end, we have established a Comprehensive Compliance Program designed to incorporate key elements set out in the Compliance Program Guidance for Pharmaceuticals issued by the U.S. Department of Health and Human Services Office of Inspector General (OIG). The OIG’s Compliance Program Guidance provides relevant information for healthcare company compliance programs.

The purpose of our Company’s Comprehensive Compliance Program is to prevent, detect, and remediate violations of Company standards and applicable law. We describe below the fundamental elements of the Company’s Comprehensive Compliance Program, which has been tailored to fit our Company’s size and resources, as well as the unique interactions that the Company has as a distributor of dental and medical products. As envisioned by OIG’s *Compliance Program Guidance*, the Company endeavors to continually improve its Comprehensive Compliance Program in response to ever-evolving business activities, applicable laws, and associated compliance risks.

COMPREHENSIVE COMPLIANCE PROGRAM ELEMENTS

- **Written Policies and Procedures**

We have adopted written policies and procedures that provide guidance to our employees in their dealings with health care professionals, customers, suppliers, government entities, society at large, and other third parties. The basis of our written standards is our Company’s Employee Handbook including our policy governing marketing and sales interactions with healthcare professionals. In addition, in accordance with California law, our Company has set an annual dollar limit on gifts, promotional materials, and items of value that the Company provides to each individual California health professional (\$2500 per covered recipient per year).

- **Leadership and Oversight**

The Company’s management team has overall responsibility for managing and overseeing the Compliance Program.

- **Training and Education**

Our Company is committed to effectively communicating our standards and procedures to Company personnel. Our Company periodically reviews and updates its training programs, and identifies additional areas of training on an “as needed” basis.

- **Communication**

Our Company encourages open and candid discussion between management and employees regarding any compliance concerns. Employees can turn to any member of management to express their concerns. Our goal is that all employees, when seeking answers to questions or reporting potential instances of misconduct, should know to whom to turn for a meaningful response and should be able to do so without fear of retaliation.

- **Risk Assessment, Auditing, and Monitoring**

Our Company may conduct internal company audits periodically to evaluate adherence to the Company’s standards. The nature of our reviews, as well as the extent and frequency of our monitoring and auditing, varies

according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations.

- **Enforcement and Disciplinary Measures**

We conduct fair and diligent investigations of compliance matters that are brought to the Company's attention. Our Company takes disciplinary actions, where appropriate, in response to confirmed violations of the Company's compliance standards, and strives to ensure consistent application of the Company's standards.

- **Responses to Detected Problems and Corrective Actions**

An effective compliance program increases the likelihood of preventing and detecting unlawful and unethical behavior. However, even an effective compliance program may not prevent all violations. Accordingly, the Company's Comprehensive Compliance Program requires a prompt response to potential violations of law or Company policy. Actions in response to detected problems, and to prevent future violations, may include improving policies or procedures, training, communication and monitoring or disciplinary action.

CALIFORNIA HEALTH AND SAFETY CODE §§119400-119402

The Company has adopted a Comprehensive Compliance Program guided by OIG's *Compliance Program Guidance for Pharmaceutical Manufacturers* and industry standards. We tailored our Comprehensive Compliance Program to the nature of our business as a distributor of dental and medical products. The California law makes reference to compliance with the *PhRMA Code on Interactions with Healthcare Professionals (PhRMA Code)*, which is an industry standard that applies to pharmaceutical manufacturers and does not reflect the unique nature of distributor activities. We have, accordingly, not adopted the *PhRMA Code*, but instead have adopted a marketing code of conduct intended to help ensure our compliance with applicable laws and regulations and consistent with industry standards for distributors.

We believe that our Company has developed a Comprehensive Compliance Program that meets the compliance goals set forth by California Health and Safety Code sections 119400 through 119402. To our knowledge, we are, in all material respects, in compliance with our Comprehensive Compliance Program and the requirements of California Health and Safety Code sections 119400 through 119402, as we interpret and apply the requirements to the nature of our business. Although we are not making a representation that every employee and agent will always fully comply with our standards and rules, our Comprehensive Compliance Program is reasonably designed to prevent and detect violations. We are committed to monitoring our conduct and taking appropriate action to discipline Company personnel who violate our standards.

Requests for copies of this declaration and for any questions regarding it, please contact the Company via email at regulatory@topqualitygloves.com or by visiting the company website.