Hongkong Kannry Industrial Co., Ltd.

Kannry Bio (www.kannrybio.com)

QUALITY STATEMENT

For bioactive ceramics & powder materials

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1. Purpose

Hongkong Kannry Industrial Co., Ltd. (brand: Kannry Bio) is committed to supplying consistent, traceable bioactive inorganic materials and powder solutions for orthopedic, dental and regenerative medicine development programs. This statement summarizes our quality practices and document support for customer evaluation and qualification.

2. Quality Management System

- We implement a quality management system with controlled documentation, defined responsibilities and process monitoring.
- Key inputs (raw materials), critical process parameters and release criteria are managed under controlled procedures.
- Deviations, changes, complaints and CAPA (Corrective and Preventive Actions) are handled through documented workflows with records retained.

3. Batch Release & Traceability

- Each lot/batch is assigned a unique Lot/Batch No. enabling traceability from incoming materials through manufacturing and final release.
- Release documentation may include COA (Certificate of Analysis), shipping records and retention sample records (as applicable).
- Critical attributes requested by customers—such as particle size, surface area, phase composition, and impurity/trace elements—are tested or verified per agreed scope.

4. COA and Data Provision Principles

- Public-facing materials may include typical values or sample/illustrative COA formats (optionally watermarked) for technical communication.
- Full batch-specific COA (Full COA) and associated method details/conditions can be provided via email or under mutually agreed documentation terms.
- Results can vary with test methods and sample preparation. When needed, qualification and release decisions should follow the method/conditions agreed by both parties.

5. Change Control

- Changes to critical raw materials, key suppliers, critical process steps or critical test methods are reviewed and approved internally.
- For changes impacting customer-defined critical requirements, we will communicate within a reasonable timeframe based on project agreements.

6. Public Disclaimer

This statement describes our quality practices and document support capabilities. It does not constitute a claim of regulatory approval, clinical performance, or suitability for any specific finished medical device indication. Regulatory and clinical responsibilities for finished products remain with the finished-product owner.

7. Contact

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