



## **Statement of Corporate Independence & WHO Code Compliance**

Submitted by: Kaizen Biotech Ltd. Product: Flow (Insight-Based Breastfeeding Support Tool)

### **1. Executive Summary: Our Mission**

Kaizen Biotech is an independent research and development (R&D) company dedicated to a single mission: extending the duration of direct breastfeeding.

We recognize that maternal anxiety regarding milk supply is a primary driver of early breastfeeding cessation. Our technology, Flow, is designed as a clinical educational tool. It provides visual biofeedback to reassure mothers of milk transfer, empowering them to overcome anxiety and sustain their direct breastfeeding relationship.

### **2. Compliance with the International Code of Marketing (WHO Code)**

Kaizen Biotech unequivocally supports the aim, principles, and recommendations of the International Code of Marketing of Breast-milk Substitutes and relevant World Health Assembly (WHA) amendments.

**No Conflicting Products:** Kaizen Biotech does not manufacture, market, or sell commercial milk formula, feeding bottles, or artificial teats.

**Commitment to Direct Breastfeeding:** Our technology is engineered exclusively to support the lactating parent and the breastfed infant.

### **3. Corporate Structure & Independence**

To ensure widespread access to our technology, Kaizen Biotech has entered into a distribution agreement with Munchkin, Inc. However, it is vital to understand the nature of this relationship:

**Operational Autonomy:** Kaizen Biotech is an independent entity. While Munchkin acts as our distributor and holds a minority shareholder position, it



does not possess majority decision-making power over Kaizen's operations, R&D pipeline, clinical protocols, or marketing strategies.

**Separation of Marketing & Education:** Kaizen Biotech retains full autonomy over the clinical data, educational materials, and professional training protocols regarding Flow.

**Strict Product Boundaries:** Kaizen Biotech's scope is limited strictly to the Flow technology. We do not support, endorse, or market any other products within the distributor's portfolio.

#### **4. Clinical Protocol: A "Bridge," Not a Barrier**

Unlike standard nipple shields often used for long-term latch issues, Flow is an educational and diagnostic device intended for intermittent use.

Flow is intended to be used only for the **moments that matter**, not for every feeding, and not for the entire session. Our professional protocol explicitly instructs clinicians to use Flow as a bridge back to the breast, not as a permanent barrier.

The "Visual Confirmation" Protocol: As detailed in our Clinical Guide for Lactation Consultants:

- **Assessment:** The clinician applies Flow to visualize milk transfer.
- **Reassurance:** The mother observes the milk flow, confirming supply and reducing anxiety. Simultaneously, the clinician uses this visual feedback to explain physiological aspects of breastfeeding, such as distinguishing between nutritive and non-nutritive sucking patterns.
- **Removal:** The protocol dictates: "Use Flow only for the moment that matters, and then remove it so the baby continues and finishes the feed directly on the breast".

This methodology ensures that the device serves to promote and preserve direct skin-to-skin contact, distinguishing it fundamentally from bottles or standard barrier devices.

#### **5. Scientific Integrity**



The core Research & Development of the Flow technology was funded directly by Kaizen Biotech.

**Technical Validation:** The distributor (Munchkin) funded an external study via an independent CRO for the purpose of Technical Due Diligence—to verify the functionality and efficacy of the technology prior to distribution.

**Kaizen Ownership:** Kaizen Biotech retains ownership of our internal R&D data, which focuses exclusively on the physiology of breastfeeding and milk transfer.

Oded Hadomi,  
Kaizen Biotech, CEO