

# Levelia Smart Watch

## Product Disclaimer & Legal Notice

*Please read this disclaimer carefully before purchasing or using the Levelia Smart Watch.*

### **IMPORTANT NOTICE**

The Levelia Smart Watch is NOT a medical device. It has NOT been evaluated, cleared, or approved by the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), or any other regulatory body. The Levelia Smart Watch is not intended to diagnose, treat, cure, monitor, or prevent any disease or medical condition, including but not limited to diabetes.

## **1. General Wellness Purpose**

The Levelia Smart Watch is a general wellness product designed to support a healthy lifestyle. Any glucose-related readings, estimates, or trend data displayed by the Levelia Smart Watch are intended solely for general wellness and informational purposes. They are NOT a substitute for professional medical advice, diagnosis, or treatment.

## **2. No Medical Claims**

The Levelia Smart Watch does NOT:

- Measure, monitor, or diagnose blood glucose levels with clinical or medical-grade accuracy
- Replace a continuous glucose monitor (CGM), blood glucose meter, or any FDA-cleared medical device
- Provide data suitable for making medical decisions, including insulin dosing, medication adjustments, or dietary changes for the management of diabetes or any other metabolic condition
- Detect, alert to, or predict hypoglycemia (low blood sugar) or hyperglycemia (high blood sugar)
- Claim compliance with ISO 15197 or any other medical device accuracy standard

## **3. Technology Limitations**

The glucose estimation feature of the Levelia Smart Watch uses optical sensor technology to provide approximate wellness trend data. This technology has inherent limitations and the readings may be affected by factors including but not limited to: skin tone, body temperature, hydration levels, physical activity, ambient light, device positioning on the wrist, perspiration, and individual physiological variation. Readings from the Levelia Smart Watch should be considered directional estimates only and may differ significantly from laboratory or clinical measurements.

## **4. Regulatory Status**

The Levelia Smart Watch has not been cleared or approved as a medical device by the FDA (United States), EMA (European Union), Health Canada, TGA (Australia), or any equivalent regulatory authority in any jurisdiction. The glucose wellness feature is classified as a general wellness function and is not subject to medical device regulation. No clinical trials have been conducted to validate the accuracy of the glucose estimation feature of the Levelia Smart Watch against reference laboratory methods.

## **5. Consult Your Healthcare Provider**

If you have diabetes, prediabetes, or any metabolic condition, you must continue to use your prescribed medical devices and follow your healthcare provider's instructions. Do not rely on the Levelia Smart Watch for any health-related decisions. Always seek the advice of a qualified healthcare professional with any questions regarding a medical condition. Never disregard professional medical advice or delay seeking it because of information displayed by the Levelia Smart Watch.

## **6. Assumption of Risk & Limitation of Liability**

By purchasing and using the Levelia Smart Watch, you acknowledge and agree that: (a) you understand the glucose estimation feature is not medically validated; (b) you will not use the Levelia Smart Watch as a substitute for professional medical advice or FDA-cleared medical devices; (c) the seller, manufacturer, and their affiliates shall not be liable for any direct, indirect, incidental, or consequential damages arising from reliance on any data displayed by the Levelia Smart Watch; and (d) any health-related decisions made based on data from the Levelia Smart Watch are made at your own risk.

## **7. Intended Use Statement**

The Levelia Smart Watch is intended for use as a general wellness and fitness tracking device by adults (18+) who wish to track general activity, heart rate trends, and wellness estimates. The Levelia Smart Watch is not intended for use by individuals who require medical-grade glucose monitoring.