

# Instructions for Use (IFU)

## Crown Emax Standard

Custom-Made Medical Device | Prescription Use Only

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### 1. Device Description

Crown Emax Standard is a custom-made prosthetic device manufactured for a single patient based on a prescription from a licensed healthcare professional. The device is supplied non-sterile.

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### 2. Intended Use

A crown is a custom-made prosthetic device intended to restore the form and function of a natural tooth. The device is Rx only, custom-made, and non-sterile.

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### 3. Indications

Restoration of the form and function of a natural tooth, as prescribed by a licensed healthcare professional using standard clinical techniques.

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### 4. Contraindications / Limitations

Not intended for removable applications.

Not intended for use when clinical conditions do not support a custom-made prosthetic restoration.

Use is limited to the scope defined in the Intended Use.

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### 5. Prescription Statement

Rx only – For use by or on the order of a licensed healthcare professional.

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## **6. Sterility**

Non-sterile.

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## **7. Warnings & Precautions**

Custom-made for a single patient only.  
Verify conformity with the prescription prior to use.  
Do not use if the device is damaged or altered.

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## **8. Storage & Handling**

Handle with care to prevent damage.  
Store at room temperature in a clean, dry environment.  
Protect from contamination prior to use.

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## **9. Manufacturer Information**

Manufacturer: Zima International, Inc. (also DBA Dandy)  
Address: N 300 W, 1320, Lehi, Utah 84043  
Country of Manufacture: United States