

### **About Us**

United Zirconia established in 2024 and it's the first Egyptian factory based in Egypt specialized in the dental materials industry, focused on the design and production of premium zirconia discs for dental professionals and laboratories. Established to meet the growing demand for high-quality, durable, and aesthetically superior dental materials, our company merges cutting-edge technology with precision manufacturing to provide superior restorative solutions.

We are proud to serve **local and international markets**, delivering products that consistently meet the highest standards in quality, strength, and aesthetics.





### Vision

To be a **leading global provider** of cutting-edge dental zirconia solutions, driving **innovation in the dental industry** while enhancing the **quality of life for patients** through advanced restorative materials.





### Mission

United Zirconia is committed to manufacturing premium dental zirconia discs that meet the highest standards of quality, durability, and aesthetics. Our mission is to empower dental professionals with reliable products that provide long-lasting and natural-looking results, promoting patient satisfaction and trust.





## Core Values & Principles

#### Our company is guided by:

- Cooperation Working together internally and with partners for shared success.
- Equality Treating every employee and client with fairness and respect.
- **Responsibility** Taking ownership of our actions and their impact on patients and the industry.





We specialize in a range of high-performance zirconia discs, suitable for:

- Crowns & Bridges
- Implant-supported restorations
- Full-contour restorations
- Anterior and posterior dental work

All products are developed using **state-of-the-art materials and technology** to ensure consistency, biocompatibility, and aesthetic excellence.





# Zircaglow HT (4Y-TZP) Preshaded Zirconia Discs





#### Indications

Best for crowns, 3-unit bridges, and cases requiring higher translucency

#### Strength

950 MPa flexural strength

Translucency

45%







#### **Delivery forms**







A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4







zircaglow

#### Indications

Ideal for posterior crowns, bridges, implant-supported restorations, and full arch restorations

#### Strength

1100 MPa flexural strength

Translucency

40%

zircaglow







### **Delivery forms**





Thicknesses
10, 12, 14, 16, 18, 20, 22, 25 mm

A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4 In addition to bleaching shades BL1 and BL3





These products are developed using **advanced processing techniques** and strict quality control to meet the evolving needs of dental professionals worldwide.







#### **Quality Assurance**

United Zirconia is committed to maintaining the **highest standards of quality control**. Our facilities operate under stringent quality management systems, ensuring:

- Precision manufacturing with minimal tolerances
- Compliance with international dental material standards
- Regular calibration and testing for product consistency



This is to certify that

#### **United Zirconia**

No.164-D, Chemical Industries Zone, North Katameya Road, Ein Sokhna, Third Settlement, 12581, Cairo, Egypt.

has been assessed by RICL and found to comply with the requirements of

ISO 13485: 2016

**Medical Devices - Quality Management Systems** 

For the following activities:

MANUFACTURING OF DENTAL RESTORATIVE PRODUCTS.

This Certificate is Valid from 25/09/2024 Until 24/09/2025

Date of Initial Certification: 25/09/2024 Ist Surveillance on or before: 24/08/2025 IInd Surveillance on or before: 24/08/2026 Certification Valid Until: 24/09/2027









Troll atour

Director
Royal Impact Certification Ltd.

This certificate can be verified at www.iafcertsearch.org, www.uafaccreditation.org or at www.ricliso.com
United Accreditation Foundation INC, 400 North Center Dr Ste 202,

623, Tower-B, iThum, Plot No. A - 40, Sector - 62, Noida 201301, India. www.ricliso.com, info@ricliso.com Phone: +91 120 4113893

UAF is member of International Accreditation Forum (IAF). Its membership status can be verified at www.iaf.nu. This Certificate remains the property of Royal Impact Certification Limited. Must be returned on request or if certificate is withdrawn. Validity of this certificate is subject to successful surveillance audits as per dates given above. TA - A 1.1





May 12, 2025

United Zirconia
% Tim Torbenson
Owner
T² & Company
1 Baya Street
Rancho Mission Viejo, California 92694

Re: K250393

Trade/Device Name: ZircaGlow & ZircaGlow HT Zirconia

Regulation Number: 21 CFR 872.6660

Regulation Name: Porcelain Powder For Clinical Use

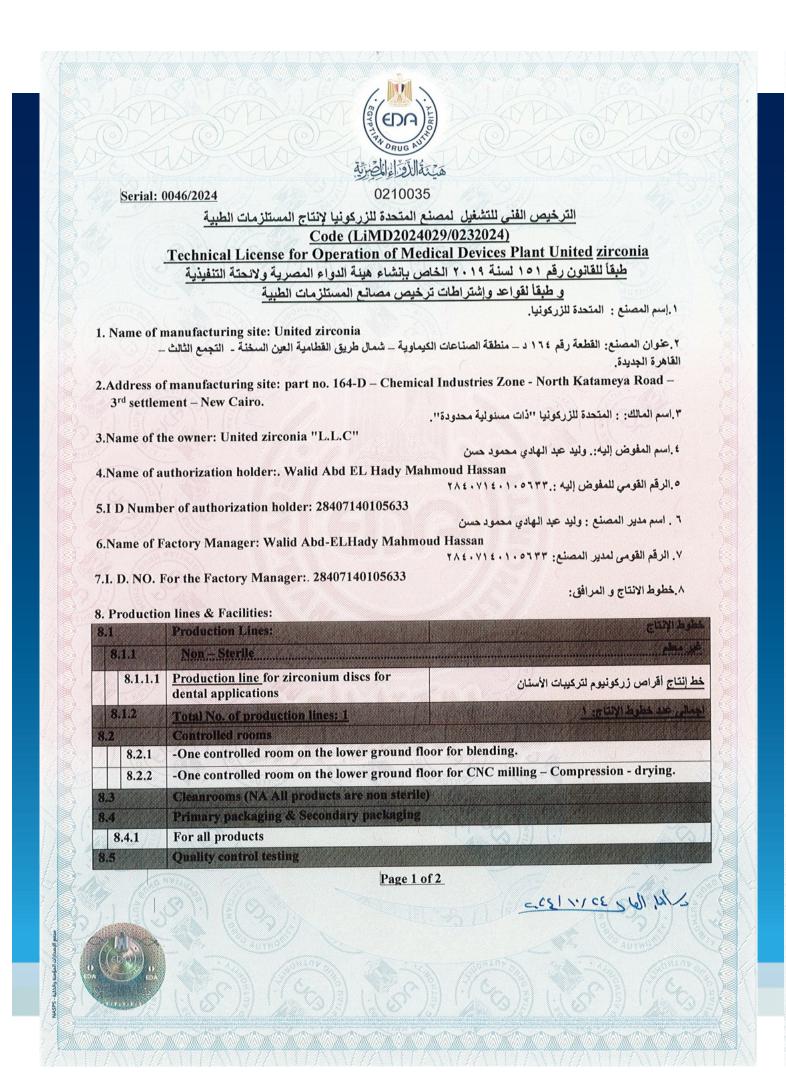
Regulatory Class: Class II Product Code: EIH Dated: February 11, 2025 Received: February 12, 2025

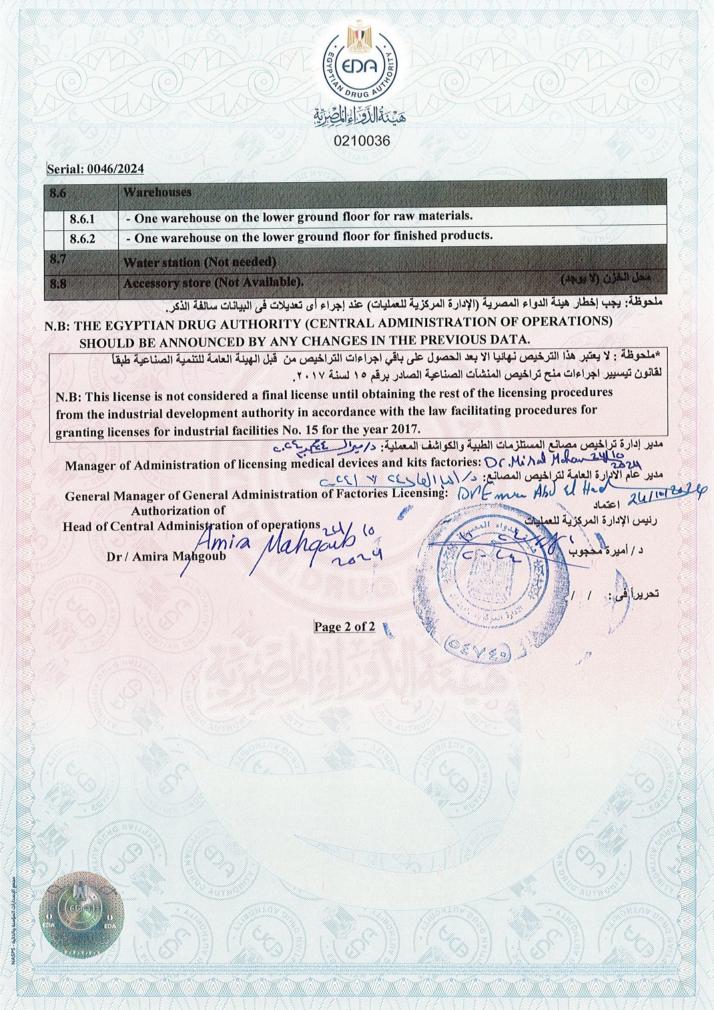
#### Dear Tim Torbenson:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm</a> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

"#\$#%&&(!)\*+, \tilde{\}'.\0/12\*32/&0!
45657!89: !;3.<1=/\*9!->90+9
\$/E>9\$<\*/0,FG) ! H5667!!
:::#1'3#.&>\_!







### Global Reach

Our commitment to excellence has positioned us to serve dental professionals and laboratories across diverse global markets. We actively participate in international dental exhibitions and collaborate with worldwide distributors and OEM clients.





#### **Contact Us**



Discover how our Preshaded **Zirconia Discs** can elevate your dental practice or lab

Contact **United Zirconia** today for more information, samples, or to place an order

+20 1500184110



164D, Chemical industries zone, North Kattameya Road 3<sup>rd</sup> Settlement, New Cairo, Egypt

contact@unitedzirconia.com www.unitedzirconia.com