

Shenzhen Yurucheng Dental Materials Co., Ltd.

<b>Document name</b>	<b>User Manual Dental Lithium Disilicate Glass-Ceramics (MDR)</b>			<b>Edition</b>	<b>A.2</b>
<b>Preparation department</b>	<b>Technical department</b>	<b>Document No.</b>	<b>YRC-RD-WI-1655</b>	<b>Page</b>	<b>Page 1 OF 12</b>

# User Manual

**Product:** Dental Lithium Disilicate Glass-Ceramics

**Model:**HT,LT

Prepared by: 吴师	Date: 2026.03.05
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## Dental Lithium Disilicate Glass-Ceramics

### User Manual

**Caution: The device is prescription use. Federal law restricts this device to sale by or on the order of a physician.**

**【Product Name】** Dental Lithium Disilicate Glass-Ceramics

#### **【Device Description】**

Dental Lithium Disilicate Glass-Ceramics is composed of  $\text{SiO}_2$ ,  $\text{Li}_2\text{O}$ ,  $\text{K}_2\text{O}$ ,  $\text{P}_2\text{O}_5$ ,  $\text{Al}_2\text{O}_3$  and other oxides. The block is intended to be processed into the dental restorations such as crowns, bridges, veneers, inlays and onlays based on the anatomical rendering of the patient's teeth using CAD/CAM (computer aided design / computer aided manufacturing) method or manual milling method. The block is a single-use device and provided non-sterile.

#### **【Models and Specifications】**

Dental Lithium Disilicate Glass-Ceramics is divided into four main categories (HT, LT). HT indicates high Transmittance and LT indicates low Transmittance.

For Color, the shade of the entire Dental Lithium Disilicate Glass-Ceramics is identical, and the model is identified by the shade Transmittance, e.g. HT-A1.

Each model has different specifications based on the shape and dimensions. The available shapes include cylinder, cuboid. The dimensions can be custom, and the dimension should be within 200mm.

#### **【Shapes, Dimensions and Color coding】**

**Table 1 Shapes, Dimensions and Color coding**

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Model		Specification	
Transmittance	Color coding	Shape	Dimension (mm)
HT	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4, OM1, OM2, OM3.	Cylinder(D×H)	10×12.5, 11×12.5, 13×12.5
	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4, OM1, OM2, OM3.	cuboid (L×W×H)	18×15×13, 40×15×15, 15.5×11×13
LT	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4, OM1, OM2, OM3.	Cylinder (D×H)	10×12.5, 11×12.5, 13×12.5
	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4, OM1, OM2, OM3.	cuboid (L×W×H)	18×15×13, 40×15×15, 15.5×11×13

### 【Chemical Compositions】

SiO<sub>2</sub>, Li<sub>2</sub>O, K<sub>2</sub>O, P<sub>2</sub>O<sub>5</sub>, Al<sub>2</sub>O<sub>3</sub> and other oxides

### 【Intended Use】

Once finalized into a suitable design, the Dental Lithium Disilicate Glass-Ceramics are indicated for use as inlays, onlays, veneer, partial crowns and crowns.

### 【Indications】

HT and LT series (40×15×15) anatomically reduced and fully anatomical (monolithic) crowns in the anterior tooth range (e.g. single-tooth crowns, inlays, onlays, veneers), from single crown to up to 3-unit teeth, i.e. the manufacturing of.

HT and LT series (18×15×13) anatomically reduced and fully anatomical (monolithic) crowns in the anterior tooth range (e.g. single-tooth crowns, inlays, onlays, veneers), from single crown to up to 2-unit

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teeth, i.e. the manufacturing of.

HT and LT series (15.5×11×13,10×12.5,11×12.5,13×12.5) anatomically reduced and fully anatomical (monolithic) crowns in the anterior tooth range (e.g. single-tooth crowns, inlays, onlays, veneers),single crown, i.e. the manufacturing of.

### **【Target Patient Population】**

Suitable for patients of all ages and gender.

### **【Intended Users】**

The Dental Lithium Disilicate Glass-Ceramics shall be processed by dental technicians. And the prepared restorations shall be handled by certified dental professionals.

### **【Intended Environment】**

The Dental Lithium Disilicate Glass-Ceramics shall be processed in dental laboratories. And the prepared restorations shall be handled in dental departments in hospitals or dental clinic with the environment clean.

### **【Clinical Benefit Of The Product】**

- \_ Restoration of missing tooth and masticatory apparatus portions;
- \_ Restoration of chewing function;
- \_ Tooth aesthetics Restoration.

### **【SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)】**

The SSCP of the products (according to the requirements of Regulation (EU) 2017/745) can be downloaded from **\*\*\* (EUDAMED websit)**.

### **【Undesirable Side Effects/Residual Risks】**

- \_ Mechanical failure (fracture of the restoration, chipping of the ceramic veneer or detachment of the restoration/loss of retention) with low risk of possible ingestion or reversible mucosal injuries.
- \_ Biological incompatibility (plaque accumulation, intolerance reactions, marginal/secondary caries, loosening of the supporting teeth) resulting in possible loss of the restoration.

### **【Physicochemical Properties】**

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**Table 2 Physicochemical Properties**

<b>Model</b>	<b>Classification (per ISO 6872:2024)</b>	<b>Density (post sintering) (g/cm<sup>3</sup>)</b>	<b>Flexural strength (post sintering) (Mpa)</b>	<b>Chemical solubility (post sintering) (μg.cm<sup>-2</sup>)</b>	<b>Radiactivity (Bq.g<sup>-1</sup>)</b>	<b>Coefficient of thermal expansion (×10<sup>-6</sup> K<sup>-1</sup>)</b>	<b>Glass transition temperature(°C)</b>	<b>Fracture toughness(MPa·m<sup>1/2</sup>)</b>
HT, LT	Type II, Class 3	2.4~2.7	≥300	<100	≤1.0	(10.5±0.5)	Tg:500±20	≥1

**【Compatible milling systems】**

**Table 3 Applicable Milling System**

<b>Serial No.</b>	<b>Brand</b>	<b>Applicable Milling System</b>
1	YUCERA	YRC-6X
2	YUCERA	YRC-5D
3	YUCERA	SK-5W

**【Compatible device】**

**Table 4 Compatible device**

<b>S/N</b>	<b>Compatible device</b>	<b>Brands</b>	<b>Usage method</b>
1	Glaze	Ivoclar,CZR	Please follow the technical instructions of the device manufacturer
2	Porcelain powders	Ivoclar,CZR	
3	Cements	Ivoclar, Bisco,DENTEK	

**Note: It is recommended to select the recommended compatible device Or have been registered and certified for medical devices**

**【Instruction for Use】**

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This product is suitable for CAD/CAM processing equipment. The processed semi-finished product is completely crystallized in the porcelain oven (840~850°C), and then made into a finished product by other processes, and then used by professional doctors for human denture or tooth restoration.

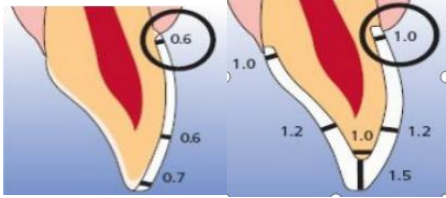
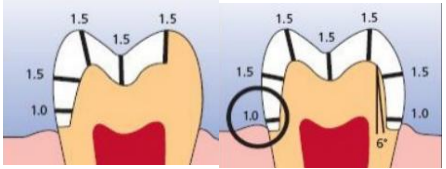
After sintering and crystallization, the finished restoration will be made after dressing, overlaying decorative porcelain or glazing and other processes as needed. If decorative porcelain, glaze and other products are used with the restoration, please follow their manufacturer's technical instructions.

**Table 5 Instruction for Use**

Use process	Matters needing attention	Tips
Porcelain selection	Factors to consider: ① Expected tooth color ② Preparative body, bridge base color ③ Restoration type ④ The thickness of the prosthesis and the depth of the preparation ⑤ Treatment process (dyeing process, post-cutting process) ⑥ Bonding material color	Shoulder preparation: Can not be prepared in the corner and sharp edge area, the shoulder should be prepared as a rounded inner edge or bevel. 2. Cutting edge preparation: It is required to reserve 1mm space to ensure that the porcelain block can achieve the ideal grinding effect during CAD/CAM processing. Incisal edge preparation should be located in the enamel layer and avoid preparation at stress concentrated points or areas.
Scan	An intraoral scanner with an accuracy of less than 30 microns was used to obtain the corresponding intraoral data model, and the scan data was transmitted to the CAD/CAM design software for the restoration design.	Dental preparation
Design	Dental CAD/CAM software was used to design the prosthesis. The shrinkage rate of glass ceramic is 0.2%, and it is recommended that the software design should be carried out in a 1:1 ratio during the restoration design process.	End face:                      Anterior crown:

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Type setting	<p>When the typesetting software is used for typesetting operation, the specifications of glass ceramics in the software should be consistent with the actual specifications of glass ceramics; If there is no identical specification, the selected specification data in the software should be slightly larger than the actual specification.</p> <p>In the layout, the connecting rod should be conical, and the cross-sectional area of the connecting restoration is 2.5-3.0mm<sup>2</sup>, and the cross-sectional area of the connecting porcelain piece is 4.0-5.0mm<sup>2</sup>.</p>	 <p>Partial crown:      Posterior crown:</p>
Cutting	<ol style="list-style-type: none"> <li>1. Use professional dental CAD/CAM cutting equipment for cutting to ensure uniform cutting on all sides of the porcelain block.</li> <li>2. The cutting process must ensure that the cutting fluid is sufficient and can be completely sprayed at the needle tip.</li> <li>3. During the cutting process, the air pressure should be maintained at 6-8bar, and the whole process requires no water and no oil to avoid pollution.</li> </ol>	 <p>3. Embedded system:</p>
Morphological trimming	<p>Please trim the shape of the restoration before calcination, i.e. when the glass ceramic is in purple state. Avoid heat generation in the grinding process, and ensure uniform force on all surfaces of the restoration to avoid hidden cracks. The minimum thickness of the polished prosthesis should be within the specified range.</p>	<p>① The depth of the embedded system shall not be less than 1mm; The width of the separation edge in the groove area shall not be less than 1mm.</p> <p>② High inlay system preparation: the preparation depth of high inlay shall not be less than 1mm; The width of the separation edge in the groove area shall not be less than 1mm; Tooth tip width shall not be less than 1mm.</p>
Sintering	<p>This product is blue purple before sintering, and will crystallize into the selected color of the restoration after sintering. Please strictly control the sintering temperature and time according to the calcination curve.</p>	<p>Inlays:                      High Inlays:</p>
Glazing	<p>Glazing is performed using dental professional dye glazing paste. After dyeing and glazing, strictly follow the sintering curve for sintering operation.</p>	

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### 【Suggested Sintering Curve】

Sintering can take place in all common dental sintering furnaces which are approved for the sintering of restorations made of Dental Lithium Disilicate Glass-Ceramics. Since Dental Lithium Disilicate Glass-Ceramics is known to be a poor thermal conductor, it is recommended that you slowly heat the mounts to the required temperature (see Table 6- Table 8) and cool them down equally slowly.

### 【Recommended Sintering Curve】

**Table 6 One-stage crystallization procedure**

Starting temperature (°C)	Drying time (s)	Heating rate (°C/min)	Maximum temperature (°C)	Holding time (s)	Vacuum starting temperature (°C)	Vacuum end temperature (°C)
400	360	45	840	420	550	840

**Table 7 Two-stage crystallization program**

Starting temperature (°C)	Drying time (s)	Heating rate (°C/min)	Hold temperature (°C)	Holding time (s)	Vacuum starting temperature (°C)	Vacuum end temperature (°C)
400	360	45/30	820/840	10/420	550	840

**Table 8 Glazing Procedure**

Starting temperature (°C)	Drying time (s)	Heating rate (°C/min)	Hold temperature (°C)	Holding time (s)	Vacuum starting temperature (°C)	Vacuum end temperature (°C)

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400	30	40	840	180	550	840
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### 【Contraindication】

1. Do not use for those allergic to glass ceramic materials and patients with oral mucosa ulcer;
2. This product is not suitable for making four Bridges;
3. Can not be used for serious heart, liver, kidney, hematopoietic system and other diseases and mental patients;
4. Not for those with untreated oral diseases;
5. Cannot be used for some special groups such as pregnant women;

### 【Warning】

1. According to the different clinical use, choose the appropriate production materials.
2. During the grinding process, the operator should wear a mask to prevent ceramic dust inhalation.

### 【Caution】

1. Avoid collision with hard objects, avoid severe extrusion, force and vibration during handling;
2. Can not be directly used for human denture or oral repair without complete crystallization;
3. Dust protection is required during the use of the product, and 3M dust masks and goggles are recommended. In case of accidents during normal use of the product, please close the processing machine in time, and adjust the processing machine to make dentures after the product is stable;
4. This product needs to be made by professional technicians and fitted, adjusted and worn by professional doctors;
5. This product is a disposable product;
6. The product is made of dentures and put into the patient's mouth. The patient should not chew hard objects and maintain clean oral hygiene;
7. In the process of product processing, it is forbidden to spray open fire or other ignition sources;
8. In case of skin contact, rinse immediately;
9. Seek medical attention immediately if skin rash or allergic symptoms appear;
10. It is prohibited to carry out ceramic processing without post training personnel.

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### 【Precaution】

1. Please check well the package and inside product, If only the packaging is damaged, the product can be used if it is not damaged, and otherwise it cannot be used.
2. Don't press and collide during store, transit and processing.
3. When choosing the devices and equipment in combination, please strictly comply with the requirements in "Compatible Devices and Equipment". Otherwise, the performance of restorations may be affected.
4. Restorations that aren't sintered should not be directly used in human denture or oral repair.
5. This product needs to be made by professional technicians and used by professional doctors.
6. When milling the blank or cutting, grinding and polishing the restorations, wear an approved dust respirator to protect your lungs from inhaling dust.
7. Expired product is forbidden to use.
8. Do not reuse the restoration. There may be cracks in the reused restorations, even invisible small cracks may bring the risk of fracture of the restoration. In addition, if a restoration is reused between different patients, there are mainly two additional risks: 1) cross-infection, 2) mismatch between the restoration prepared for one patient and the base teeth of another patient, which can badly effect the restoration.
9. Please storage the products in the conditions as specified in "STORAGE", otherwise the performances of the product may be affected.
10. Wall and edge thickness

**Table 9**

Type	Anterior	Connector cross section	Posterior	Connector cross section
	Thickness		Thickness	
Single crown	≥0.9mm	≥9mm <sup>2</sup>	≥1.0mm	≥12mm <sup>2</sup>
3 unit bridges	≥0.9mm			
Long bridges	≥0.9mm			

### 【Disposal】

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1. The residual materials after product processing need to be collected uniformly and transferred to the relevant waste recycling agency for treatment, and the waste itself does not cause environmental pollution.
2. The discarded prosthetics that have not been used in the patient's mouth can be handed over to the relevant waste recycling agency together with the processed residual materials, which does not pollute the environment.
3. The discarded prosthetics removed from the patient's mouth should be collected in a yellow medical trash can with a lid and set in a special yellow medical garbage bag. When the container is 3/4 full, the garbage bag should be sealed and labeled with a special label, and disposed of as medical waste to avoid biological hazards and cross-infection caused by misuse or contact.
4. Other requirements Dispose of according to local regulations.

### 【Storage】

This product should be stored in a clean and dry room with no corrosive gases, good ventilation.

**【Shelf Life】** 10 years.



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### 【Symbols】

	Do not re-use		Fragile, handle with care		Use-by date
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	Prescription only		Caution		Batch code
	Keep dry		Date of manufacture		Consult instructions for use
	Manufacture		CE marking		Medical device

### 【Release date and VER】

Release date: March 5, 2026

VER:A.2

### 【Notice】

To users:

Please report any serious incident that has occurred in relation to the device to Shenzhen Yurucheng Dental Materials Co., Ltd. and the competent authority of the Member State of residence.

### Revision history

	Version	Revision date	Revised by	Description of revised contents
Revision history	A.0	March 3, 2024	Liu Wei	Original release
	A.1	August 30, 2024	Liu Wei	Product-specific standard EN ISO 6872:2015 is replaced by EN ISO 6872:2024.
	A.2	March 5, 2026	Wu Shi	1.Update Address; 2.Product name change; 3.Delete the models ML-HT and ML-LT