User Manual Dental Lithium Disilicate Glass-Ceramics（MDR）

（Edition：A.4）

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Distribution department	☐ HR department ☐ Technology department ☐ Purchasing department ☐ Production department ☐ Quality assurance department ☐ System department ☐ Planning department ☐ Warehouse department ☐ Marketing department ☐After-sales department ☐Equipment department ☐Others _____

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 SiO_2, Li_2O， K_2O,P_2O_5,Al_2O_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

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, BL4，0M1, 0M2, 0M3.	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, BL4，0M1, 0M2, 0M3.	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, BL4，0M1, 0M2, 0M3.	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, BL4，0M1, 0M2, 0M3.	cuboid (L×W×H)	18×15×13,40×15×15, 15.5×11×13

In order to facilitate users to identify the dimension of the product without labels, dimensions are encoded as alphanumeric identifiers:

Code	L×W×H (mm)
B40	40×15×15 mm
C14	18×15×13 mm
I12	15.5×11×13 mm

【Chemical Compositions】

SiO_2, Li_2O，K_2O,P_2O_5,Al_2O_3 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 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】

Adults patients with permanent teeth, not for pregnant or breast feeding women.

【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】

Table 2 Physicochemical Properties

Model	Classification (per ISO 6872:2024)	Density (post sintering) (g/cm^3)	Flexural strength (post sintering) (Mpa)	Chemical solubility (post sintering) ($\mu g.cm^{-2}$)	Radioactivity ($Bq.g^{-1}$)	Coefficient of thermal expansion ($\times10^{-6} K^{-1}$)	Glass transition temperature(℃)	Fracture toughness($MPa\cdot m^{1/2}$)
HT, LT	Type II, Class 3	2.4 ～ 2.7	≥300	＜100	≤1.0	（10.5±0.5）	Tg:500±20	≥2

【Compatible mmilling systems】

Table 3 Applicable Milling System

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

【Compatible device】

Table 4 Compatible device

S/N	Compatible	Brands	Usage method

	device		
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】

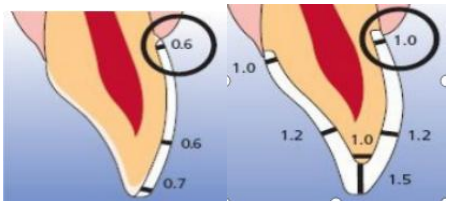
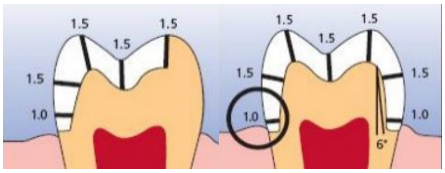
Processing Instructions for Products with Handle：

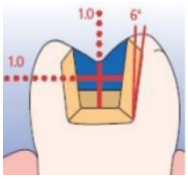
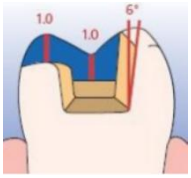
This product is suitable for CAD/CAM processing equipment. The processed semi-finished product is completely crystallized in the porcelain oven (840~850℃), and then made into a finished product by other processes, and then used by professional doctors for human denture or tooth restoration.

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 ③Restoration type ④The thickness of the prosthesis and the depth of the preparation	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.

	⑤Treatment process (dyeing process, post-cutting process) ⑥ Bonding material color	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. Dental preparation End face： Anterior crown：  Partial crown: Posterior crown:  3. Embedded system: ① The depth of the embedded
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.	
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.	
Type setting	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. In the layout, the connecting rod should be conical, and the cross-sectional area of the connecting restoration is 2.5-3.0mm2, and the cross-sectional area of the connecting	

	porcelain piece is 4.0-5.0mm2.	system shall not be less than 1mm; The width of the separation edge in the groove area shall not be less than 1mm.
Cutting	1. Use professional dental CAD/CAM cutting equipment for cutting to ensure uniform cutting on all sides of the porcelain block. 2. The cutting process must ensure that the cutting fluid is sufficient and can be completely sprayed at the needle tip. 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.	②High 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. Inlays： High Inlays：  
Morphological trimming	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.	

Sintering	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.	
Glazing	Glazing is performed using dental professional dye glazing paste. After dyeing and glazing, strictly follow the sintering curve for sintering operation.	

Processing Instructions for Products without Handle

Usage Process	Precautions	Tips
Porcelain Block Selection	Select appropriate - colored porcelain blocks for use according to the tooth shade information and abutment information provided by the doctor.	/
Wax Pattern Making	Wax patterns can be made by manual wax - dripping, cutting, and 3D printing.	The marginal seal of the restoration must be ensured. 
Inserting Sprue	1. Determine the weight of the wax pattern before investment,	1. Different restorations require different mixing ratios of investment materials.

	and select appropriate porcelain blocks (must be brand - new and clean). One porcelain block can be used for wax pattern restorations weighing ≤ 0.7g. 2. Select a 100g or 200g investment ring system according to the weight and volume of the investment material. Dental bridges must use a 200g investment ring system. 3. Start inserting the sprue. 4. Completion of sprue insertion.	Therefore, not all restorations can have sprues inserted and be invested. 2. There should be at least a 10mm distance between the wax body and the wall of the investment ring. The maximum height (wax body + casting) must not exceed 16mm. 3. If there is only one investment body, a second short sprue must be fixed to ensure that the pressure - casting furnace can stop working at the end of the pressure - casting process. 
Embedding	Operation steps: 1） Evenly apply a separating agent on the inner wall of the embedding ring and the surface of the base. 2） Prepare the embedding material according to the proportion required by the	1. Never use any cleaning agents on the wax pattern. 2. The processing temperature of the investment material is 18 - 23°C. Temperatures that are too high or too low will affect solidification. 3. When mixing the investment material, note that the investment material contains

	embedding material. 3） Stir the embedding material under vacuum (for 40 - 60 seconds). 4） Carry out the embedding. 5）The embedding is completed.	quartz powder. Therefore, avoid inhaling the dust. 4. Use appropriate tools to accurately invest the cavity (such as a small brush) to ensure that the wax pattern edges are not damaged. 5. Place the silicone rubber ring carefully at the bottom of the investment ring without damaging the wax pattern. The silicone rubber ring must be seamlessly attached to the base of the investment ring. 6. Always follow the time specified in the investment material instruction manual for solidification. 7. To prevent the investment material from cracking, the investment must be processed within 24 hours.
Ring Firing	Operation Steps 1. Turn on the muffle furnace and raise the temperature to 850 - 860 °C (raise the temperature according to the temperature specified for the embedding material used).	 1. The porcelain block and the alumina push rod do not need to be preheated.

	2. Rotate to remove the silicone rubber ring and the ring base, and carefully push the embedding ring out of the silicone rubber ring. 3. Use a gypsum knife to remove the rough points on the bottom surface of the embedding ring. Check the 90° angle. Make sure that the residue of the embedding material does not enter the casting port. If foreign matter enters, blow it out. 4. Place the embedding ring in the furnace chamber. The sintering time depends on the size of the embedding ring and the embedding material. (For a 100g embedding ring, the minimum sintering time is 45 minutes; for a 200g embedding ring, the minimum sintering time is 60 minutes.)	2. When firing the ring, the embedding ring must be close to the rear of the furnace chamber, with the casting port tilted downward.
Die Casting	Operation Steps 1. Prepare a cold push rod and a porcelain block of the required color.	1.After the preheating cycle, the time from immediately taking the embedding ring out of the muffle furnace to putting it into the die-casting furnace should not exceed

<table>
<tr>
<td></td>
<td>2. Put the push rod into the separating agent and set it aside.
3. Turn on the die-casting furnace in a timely manner to complete self-checking and preheating.
4. Select a suitable die-casting program and a casting ring of the appropriate size.
5. Put the porcelain block into the hot embedding ring.
6. Apply the separating agent to the cold push rod and then put it into the embedding ring.
7. Place the embedding ring in the center of the preheated die-casting furnace.
8. Perform die casting.
9. After die casting is completed, use tools to take the embedding ring out of the die-casting furnace. Place the embedding ring on a cooling net to cool.</td>
<td>30 seconds to prevent the embedding ring from cooling too quickly.
2.Please strictly follow the porcelain casting die-casting curve for die-casting:
For a 100g ring
HT (high translucency) die-casting curve:
<table>
<tr><th>Initial temperature(± 10)</th><th>Heating rate</th><th>Maximum temperature(± 10)</th><th>Holding time</th></tr>
<tr><td>700°C</td><td>50°C/min</td><td>930°C</td><td>15min</td></tr>
</table>
LT (Low translucency) die-casting curve:
<table>
<tr><th>Initial temperature(± 10)</th><th>Heating rate</th><th>Maximum temperature(± 10)</th><th>Holding time</th></tr>
<tr><td>700°C</td><td>50°C/min</td><td>915°C</td><td>15min</td></tr>
</table>
200g ring
HT (high translucency) die-casting curve:
<table>
<tr><th>Initial temperature(± 10)</th><th>Heating rate</th><th>Maximum temperature(± 10)</th><th>Holding time</th></tr>
<tr><td>700°C</td><td>50°C/min</td><td>930°C</td><td>20min</td></tr>
</table>
LT (Low translucency) die-casting curve:
<table>
<tr><th>Initial temperature(± 10)</th><th>Heating rate</th><th>Maximum temperature(± 10)</th><th>Holding time</th></tr>
<tr><td>700°C</td><td>50°C/min</td><td>915°C</td><td>15min</td></tr>
</table>
3.After setting the die-casting curve in the porcelain casting furnace, preheat it to 700 °C in advance. Do not accelerate the cooling, for example, by using an air gun to blow.</td>
</tr>
<tr>
<td>Removal of Embedding</td>
<td>Operation Steps
1. Mark the length of the push rod on the cold casting ring.
2. Cut the embedding ring with a</td>
<td>It is necessary to abide by the sandblasting direction and distance to prevent damage to the edges of the restoration.</td>
</tr>
</table>

Material	separating disc to separate the push rod from the ceramic material. 3. Use a gypsum knife to separate the casting ring at the predetermined breaking point. 4. Perform rough sandblasting at a pressure of 4 bar (60 psi). 5. Perform fine sandblasting at a pressure of 2 bar (30 psi). 6. Use aluminum oxide to remove the remaining impurities on the push rod. 7. The removal is completed.	
Acid Etching of the Surface	Operation Steps 1） Pour the acid etching solution into a plastic cup. 2） Immerse the die-cast object in the acid etching solution and clean it with an ultrasonic cleaner for at least 10 minutes and at most 30 minutes. 3）Take the restoration out of the acid etching solution, rinse it with tap water, and blow it dry. 4） Sandblast again (with	1. The hydrofluoric acid solution can only be contained in plastic containers and cannot be contained in glass or ceramic containers, etc. 2. When acid etching, ensure that the casting is completely immersed in the acid etching solution. 3. Replace the acid etching solution after using it about 20 times or use it again after it has settled.

	aluminum oxide) to remove the white reaction layer at a pressure of 1 - 2 bar (15 - 30 psi). Make sure that the reaction layer on both the inner and outer sides of the crown is completely removed (repeat this procedure if necessary). If the reaction layer is not completely removed, bubbles will form, which can cause bonding problems or coating cracking.	
Surface Treatment	Operation Steps 1. Cut the sprue: Moisten the grinding area before cutting. Cut the sprue with a diamond abrasive disc. 2. Use a coarse grinding bur to remove the sprue connection point and trim the shape. Grind in the same direction from right to left. This will result in delicate and regular grinding lines. Grinding in the correct direction is more efficient. Grinding in the opposite direction has a lower grinding	1. The rotational speed range for pre-polishing is 7000 - 12000 r/min. 2. The porcelain casting material must be polished to completely remove the surface reaction layer. Otherwise, problems such as white spots, white fog, lack of transparency, and low saturation will occur, affecting the aesthetic effect. 3. The pressure during the pre-polishing process should not be too high. It is not allowed to grind continuously in one position to avoid generating excessive heat that may cause hidden cracks or fractures.

	efficiency and increases the wear of the grinding head. Prepare some cold water. Dip your fingers in water and apply it to the grinding area every three grinding operations. Usually, after three spot grinding operations, the temperature of the restoration will not exceed 60 °C. After the water cools down, repeat to ensure that the temperature of the porcelain does not exceed 60 °C. Use the rotational speed of the grinding head for grinding and removal. Use the method of spot grinding. The contact time between the grinding head and the restoration each time should not exceed 1 second to avoid local overheating or stress concentration. Continuously change the position and grind multiple times. Do not grind continuously in one position. 3. Polishing: Following the steps of rough grinding, make the surface lines of the tooth neat,	

	uniform, and delicate. Similar to rough grinding, grind the entire surface in the same direction from right to left.	
Try-in	During the try-in, make sure the restoration fits accurately. Do not press it forcefully.	
Glazing	Operation Steps 1. Cleaning: Thoroughly clean the restoration with a steam or ultrasonic oscillating cleaner. 2. Dip an appropriate amount of transparent glaze with a glazing pen and evenly apply it on the surface of the restoration. 3. Sintering. 4. The case is completed.	/

【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 (℃)(±10)	Drying time (s)	Heating rate (℃/min)	Maximum temperature (℃)(±10)	Holding time (s)	Vacuum starting temperature (℃) (±10)	Vacuum end temperature (℃)(±10)
400	360	45	840	420	550	840

Table 7 Two-stage crystallization program

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

Table 8 Glazing Procedure

Starting temperature (℃)(±10)	Drying time (s)	Heating rate (℃/min)	Hold temperature (° C)(±10)	Holding time (s)	Vacuum starting temperature (℃)(±10)	Vacuum end temperature (℃)(±10)
400	30	40	840	180	550	840

【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.

【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		Posterior	
	Thickness	Connector cross section	Thickness	Connector cross section
Single crown	≥0.9mm	≥9mm²	≥1.0mm	≥12mm²
3 unit bridges	≥0.9mm			

【Disposal】

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.

Shenzhen Yurucheng Dental Materials Co., Ltd.

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【Symbols】

	Do not re-use		Fragile, handle with care		Use-by date
	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：February 28, 2026

VER:A.4

【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	Page	Description of revised contents
Revision history	A.0	July 8, 2021	15	Original release
	A.1	March 10, 2023	15	Update Address
	A.2	August 30, 2024	15	Product-specific standard EN ISO 6872:2015 is replaced by EN ISO 6872:2024.
	A.3	April 11, 2025	17	Change of the Authorized Representative Icon
	A.4	February 28, 2026	21	1.Product name change； 2.Delete the models ML-HT and ML-LT