

Declaration of Conformity

Name and address

- Manufacture Name: Liaoning Upcera Co.,Ltd
- Manufacture Address:
No.122 Xianghuai Road, Economic Development Zone, Benxi , Liaoning , P.R.C.
- Tel: +86 414 5565055
- Fax: +86 414 5854457
- Zip:117004



- Manufacture Logo:
- European Representative:

EC-REP	MEDNET GmbH
Address	Borkstrasse 10, 48163 Münster, Germany
Tel	+49 (0) 251 32266-0
Fax	+49 (0) 251 32266-22
Contact	Nicole Böhnisch , Silke Flotho-Westrup, Amy

- Conformity

As a manufacture, once the product (Dental zirconia Ceramics and Dental Lithium Disilicate Glass Ceramics, color for the staining of zirconia ceramics) into the European market, we will put the European representative's name on the products, and provide MDD agreement with EC-REP to TUV company.

MDD agreement :Appendix 1.

B Declaration of conformity

Report No.UPQ/JZ-42-0032-2013

- Manufacturer: Liaoning Upcera Co.,Ltd
- Address: No.122 Xianghuai Road, Economic Development Zone, Benxi ,Liaoning ,P.R.C.
- European Representative: MEDNET GmbH
- DIMDI Code: DE/0000012115
- Product: Zirconia Dental Ceramics
- Specification/Models: refer to Zirconia Dental Ceramics--- CE technical file.
- Classification: Class II a, Rules 8, ANNEX V, MDD

We declare under our sole responsibility that the above mentioned product meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

Standards:

EN ISO 10993-1:2020

EN ISO10993-3:2014

ENISO10993-5 2009

ENISO10993-10 2013

ENISO10993-11 2018

ISO6872 2015

All applicable harmonized standards(published in the official journal of the European Communities)

Directives: General applicable directives: Medical device Directive MDD 93/42/EEC

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

2007/47/EC

Conformity assessment moduels: Annex V

Notified Body: TUV 0197

1. Product Name, Class, Outline

1.1 Product Name: Zirconia Dental Ceramics

1.2 Class: Class II a, Rules 8, ANNEX V, MDD

1.3 Outline

Zirconia Dental Ceramics is used for dental restoration such as anterior or posterior single tooth or bridge restorations, machined by Manual or CAD/CAM milling system in professional dental restoration lab. There are two types of White Zirconia Dental Ceramics and Pre-shade Zirconia Dental Ceramics.

Country of Origin: Made in China

All below dental zirconia blanks which UPCERA send to DT&SHOP GmbH are CE certified.

Artikelnr.	Produktname	Lief.-Nr.	Lieferant	Lief.-Artnr.
0053	explore Esthetic CAD/CAM-Rohling, ø 98 x 12 mm	71458	Shenzhen Upcera Dental	
0054	explore Esthetic CAD/CAM-Rohling, ø 98 x 14 mm	71458	Shenzhen Upcera Dental	
0055	explore Esthetic CAD/CAM-Rohling, ø 98 x 16 mm	71458	Shenzhen Upcera Dental	
0056	explore Esthetic CAD/CAM-Rohling, ø 98 x 18 mm	71458	Shenzhen Upcera Dental	
0057	explore Esthetic CAD/CAM-Rohling, ø 98 x 20 mm	71458	Shenzhen Upcera Dental	
0058	explore Esthetic CAD/CAM-Rohling, ø 98 x 22 mm	71458	Shenzhen Upcera Dental	
0059	explore Esthetic CAD/CAM-Rohling, ø 98 x 25 mm	71458	Shenzhen Upcera Dental	
0060	explore Functional CAD/CAM-Rohling, ø 98 x 12 mm	71458	Shenzhen Upcera Dental	
0061	explore Functional CAD/CAM-Rohling, ø 98 x 14 mm	71458	Shenzhen Upcera Dental	
0062	explore Functional CAD/CAM-Rohling, ø 98 x 16 mm	71458	Shenzhen Upcera Dental	
0063	explore Functional CAD/CAM-Rohling, ø 98 x 18 mm	71458	Shenzhen Upcera Dental	
0064	explore Functional CAD/CAM-Rohling, ø 98 x 20 mm	71458	Shenzhen Upcera Dental	
0065	explore Functional CAD/CAM-Rohling, ø 98 x 22 mm	71458	Shenzhen Upcera Dental	
0066	explore Functional CAD/CAM-Rohling, ø 98 x 25 mm	71458	Shenzhen Upcera Dental	
0067	Hyramic Multilayer CAD/CAM-Block, 12 x 14 x 18 mm	71458	Shenzhen Upcera Dental	
0068	Hyramic HT CAD/CAM-Block, 12 x 14 x 18 mm	71458	Shenzhen Upcera Dental	
0069	Hyramic LT CAD/CAM-Block, 12 x 14 x 18 mm	71458	Shenzhen Upcera Dental	
0071	Dental Zirconia TT Multilayer CAD/CAM-Rohling, ø 98 x 12 mm	71458	Shenzhen Upcera Dental	
0072	Dental Zirconia TT Multilayer CAD/CAM-Rohling, ø 98 x 14 mm	71458	Shenzhen Upcera Dental	
0073	Dental Zirconia TT Multilayer CAD/CAM-Rohling, ø 98 x 16 mm	71458	Shenzhen Upcera Dental	
0074	Dental Zirconia TT Multilayer CAD/CAM-Rohling, ø 98 x 18 mm	71458	Shenzhen Upcera Dental	
0075	Dental Zirconia TT Multilayer CAD/CAM-Rohling, ø 98 x 20 mm	71458	Shenzhen Upcera Dental	
0076	Dental Zirconia TT Multilayer CAD/CAM-Rohling, ø 98 x 22 mm	71458	Shenzhen Upcera Dental	
0078	Dental Zirconia ST Multilayer CAD/CAM-Rohling, ø 98 x 12 mm	71458	Shenzhen Upcera Dental	
0079	Dental Zirconia ST Multilayer CAD/CAM-Rohling, ø 98 x 14 mm	71458	Shenzhen Upcera Dental	
0080	Dental Zirconia ST Multilayer CAD/CAM-Rohling, ø 98 x 16 mm	71458	Shenzhen Upcera Dental	
0081	Dental Zirconia ST Multilayer CAD/CAM-Rohling, ø 98 x 18 mm	71458	Shenzhen Upcera Dental	
0082	Dental Zirconia ST Multilayer CAD/CAM-Rohling, ø 98 x 20 mm	71458	Shenzhen Upcera Dental	
0083	Dental Zirconia ST Multilayer CAD/CAM-Rohling, ø 98 x 22 mm	71458	Shenzhen Upcera Dental	

0085	Dental Zirconia TT Color CAD/CAM-Rohling, ø 98 x 12 mm	71458	Shenzhen Upcera Dental	
0086	Dental Zirconia TT Color CAD/CAM-Rohling, ø 98 x 14 mm	71458	Shenzhen Upcera Dental	
0087	Dental Zirconia TT Color CAD/CAM-Rohling, ø 98 x 16 mm	71458	Shenzhen Upcera Dental	
0088	Dental Zirconia TT Color CAD/CAM-Rohling, ø 98 x 18 mm	71458	Shenzhen Upcera Dental	
0089	Dental Zirconia TT Color CAD/CAM-Rohling, ø 98 x 20 mm	71458	Shenzhen Upcera Dental	
0090	Dental Zirconia TT Color CAD/CAM-Rohling, ø 98 x 22 mm	71458	Shenzhen Upcera Dental	
0092	Dental Zirconia ST Color CAD/CAM-Rohling, ø 98 x 12 mm	71458	Shenzhen Upcera Dental	
0093	Dental Zirconia ST Color CAD/CAM-Rohling, ø 98 x 14 mm	71458	Shenzhen Upcera Dental	
0094	Dental Zirconia ST Color CAD/CAM-Rohling, ø 98 x 16 mm	71458	Shenzhen Upcera Dental	
0095	Dental Zirconia ST Color CAD/CAM-Rohling, ø 98 x 18 mm	71458	Shenzhen Upcera Dental	
0096	Dental Zirconia ST Color CAD/CAM-Rohling, ø 98 x 20 mm	71458	Shenzhen Upcera Dental	
0097	Dental Zirconia ST Color CAD/CAM-Rohling, ø 98 x 22 mm	71458	Shenzhen Upcera Dental	
06847	Dental Zirconia HT White CAD/CAM-Rohling, ø 98 x 12 mm	71458	Shenzhen Upcera Dental	HT D98-12
06848	Dental Zirconia HT White CAD/CAM-Rohling, ø 98 x 14 mm	71458	Shenzhen Upcera Dental	HT D98-14
06849	Dental Zirconia HT White CAD/CAM-Rohling, ø 98 x 16 mm	71458	Shenzhen Upcera Dental	HT D98-16
06850	Dental Zirconia HT White CAD/CAM-Rohling, ø 98 x 18 mm	71458	Shenzhen Upcera Dental	HT D98-18
06851	Dental Zirconia HT White CAD/CAM-Rohling, ø 98 x 20 mm	71458	Shenzhen Upcera Dental	HT D98-20
06852	Dental Zirconia HT White CAD/CAM-Rohling, ø 98 x 22 mm	71458	Shenzhen Upcera Dental	HT D98-22
06854	Dental Zirconia HT White CAD/CAM-Rohling, ø 89 x 12 mm	71458	Shenzhen Upcera Dental	HT 89-71-12
06855	Dental Zirconia HT White CAD/CAM-Rohling, ø 89 x 14 mm	71458	Shenzhen Upcera Dental	HT 89-71-14
06856	Dental Zirconia HT White CAD/CAM-Rohling, ø 89 x 16 mm	71458	Shenzhen Upcera Dental	HT 89-71-16
06857	Dental Zirconia HT White CAD/CAM-Rohling, ø 89 x 18 mm	71458	Shenzhen Upcera Dental	HT 89-71-18
06858	Dental Zirconia HT White CAD/CAM-Rohling, ø 89 x 20 mm	71458	Shenzhen Upcera Dental	HT 89-71-20
06859	Dental Zirconia HT White CAD/CAM-Rohling, ø 89 x 22 mm	71458	Shenzhen Upcera Dental	HT 89-71-22
06861	Dental Zirconia ST White CAD/CAM-Rohling, ø 98 x 12 mm	71458	Shenzhen Upcera Dental	ST D98-12
06862	Dental Zirconia ST White CAD/CAM-Rohling, ø 98 x 14 mm	71458	Shenzhen Upcera Dental	ST D98-14
06863	Dental Zirconia ST White CAD/CAM-Rohling, ø 98 x 16 mm	71458	Shenzhen Upcera Dental	ST D98-16
06864	Dental Zirconia ST White CAD/CAM-Rohling, ø 98 x 18 mm	71458	Shenzhen Upcera Dental	ST D98-18
06865	Dental Zirconia ST White CAD/CAM-Rohling, ø 98 x 20 mm	71458	Shenzhen Upcera Dental	ST D98-20
06866	Dental Zirconia ST White CAD/CAM-Rohling, ø 98 x 22 mm	71458	Shenzhen Upcera Dental	ST D98-22
06868	Dental Zirconia ST White CAD/CAM-Rohling, ø 89 x 12 mm	71458	Shenzhen Upcera Dental	ST D89-71-12
06869	Dental Zirconia ST White CAD/CAM-Rohling, ø 89 x 14 mm	71458	Shenzhen Upcera Dental	ST D89-71-14
06870	Dental Zirconia ST White CAD/CAM-Rohling, ø 89 x 16 mm	71458	Shenzhen Upcera Dental	ST D89-71-16
06871	Dental Zirconia ST White CAD/CAM-Rohling, ø 89 x 18 mm	71458	Shenzhen Upcera Dental	ST D89-71-18
06872	Dental Zirconia ST White CAD/CAM-Rohling, ø 89 x 20 mm	71458	Shenzhen Upcera Dental	ST D89-71-20
06873	Dental Zirconia ST White CAD/CAM-Rohling, ø 89 x 22 mm	71458	Shenzhen Upcera Dental	ST D89-71-22
06875	Dental Zirconia TT White CAD/CAM-Rohling, ø 98 x 12 mm	71458	Shenzhen Upcera Dental	TT D98-12
06876	Dental Zirconia TT White CAD/CAM-Rohling, ø 98 x 14 mm	71458	Shenzhen Upcera Dental	TT D98-14
06877	Dental Zirconia TT White CAD/CAM-Rohling, ø 98 x 16 mm	71458	Shenzhen Upcera Dental	TT D98-16
06878	Dental Zirconia TT White CAD/CAM-Rohling, ø 98 x 18 mm	71458	Shenzhen Upcera Dental	TT D98-18
06879	Dental Zirconia TT White CAD/CAM-Rohling, ø 98 x 20 mm	71458	Shenzhen Upcera Dental	TT D98-20
06880	Dental Zirconia TT White CAD/CAM-Rohling, ø 98 x 22 mm	71458	Shenzhen Upcera Dental	TT D98-22
06882	Dental Zirconia TT White CAD/CAM-Rohling, ø 89 x 12 mm	71458	Shenzhen Upcera Dental	TT 89-71-12

06883	Dental Zirconia TT White CAD/CAM-Rohling, ø 89 x 14 mm	71458	Shenzhen Upcera Dental	TT 89-71-14
06884	Dental Zirconia TT White CAD/CAM-Rohling, ø 89 x 16 mm	71458	Shenzhen Upcera Dental	TT 89-71-16
06885	Dental Zirconia TT White CAD/CAM-Rohling, ø 89 x 18 mm	71458	Shenzhen Upcera Dental	TT 89-71-18
06886	Dental Zirconia TT White CAD/CAM-Rohling, ø 89 x 20 mm	71458	Shenzhen Upcera Dental	TT 89-71-20
06887	Dental Zirconia TT White CAD/CAM-Rohling, ø 89 x 22 mm	71458	Shenzhen Upcera Dental	TT 89-71-22



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