

**Manufacturer:** Orodent Srl  
**SRN:** IT-MF-000030463  
**Device Name:** Orodent  
**Model:** Preshaded  
**Product Code:** ZR98XXTTY  
**BD/RDM code:** 1464343  
**CND (EMDN):** Q010699  
**BASIC UDI-DI:** 805415427 DZIRC01 JV

**Description of the Device:** Zirconia for dental use intended for the creation of prosthetic artifacts suitable for restoring the functionality and aesthetics of the masticatory apparatus.

**Risk class:** IIa, Rule 5, third indent, of Annex VIII of the Medical Device Regulation (MDR) 2017/745

**Composition%:** ZrO<sub>2</sub> 91, Y<sub>2</sub>O<sub>3</sub> 6.90 (±0.20), Hf<sub>2</sub>O<sub>3</sub> <1.8-2, Al<sub>2</sub>O<sub>3</sub> 0.05 (±0.10), SiO<sub>2</sub> ≤ 0.002, Fe<sub>2</sub>O<sub>3</sub> ≤ 0.002

**Indications for use:** The medical device is intended for the preparation of custom-made devices, by qualified expert personnel, and placement in the dental apparatus, by medical personnel, in order to restore the functionality and aesthetics of the masticatory system, in generally adult patients, under the supervision and indication of the dentist.

**How to use:** Class 5 monolithic ceramic suitable for the creation of partially or totally coated prostheses for four or more elements to be made with a CAD/CAM system.

**Limitations:** EN ISO 6872(E) table 1. Suitable for complete anatomical bridges max 2 intermediate elements.

**Minimum Thicknesses:** 0.6 mm crowns 0.8 mm bridges of 3 elements 1 mm bridges over 3 elements

**Physical characteristics of raw materials:** Crystallite size nm 36 - Particle size μm 0.44 - Particle size size 44 - Density gr/cm<sup>3</sup> 1.20

**Physical and mechanical characteristics of the finished product:** Density of the sintered product gr/cm<sup>3</sup> 6.07 - Flexural strength MPa 1200 Fracture strength MPa<sup>0.5</sup> 3.5 - Hardness (HV10) 1250 - CET (25°C – 100°C) K-1 10x10-6 - Aging μm 4 - Translucency 45%

L.O.I. wt% 4 - BET m<sup>2</sup>/g 10 - Elasticity 200 - Sintering temperature 1,430°C opaque effect 1,530°C translucent effect

**Storage and Precautions:** Store in the original packaging until complete use and in normal environments without special precautions (ventilated and dry place).

**Marking:**  0051

#### Legend:

**SRN:** Unique Registration Number (EUDAMED)

**BD/RDM:** Medical Device Database

**CND (EMDN):** National Classification of Medical Devices (European Nomenclature of Medical Devices)

**BASIC UDI-DI:** Manufacturer's primary identifier for medical device family

**CET:** coefficient of thermal expansion

**L.O.I.: Weight loss** (1000°C)

**BET:** Determination of specific area

**e-modul:** modulus of elasticity



For the choice of processing methods and type of materials, consult the Zirconia LAVCAMZR user manual available online on the [www.oro<sup>dent</sup>.com](http://www.oro<sup>dent</sup>.com) website or request it directly at 045/6450635 or email [sales@oro<sup>dent</sup>.com](mailto:sales@oro<sup>dent</sup>.com).