

Manufacturer: OroDent Srl Via M.G. Agnesi 8-10 37014 Castelnuovo del Garda (VR) Italy

SRN: IT-MF-000030463

Device Name: OroDent

Model: Bleach

Product Code: ZR98XXT4

BD/RDM code: 1741623

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_2 91, Y_2O_3 6.95 (± 0.20), Hf_2O_3 <1.8-2, Al_2O_3 0.05 (± 0.10), SiO_2 ≤ 0.002 , Fe_2O_3 ≤ 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 measurement nm 36 - Particle size μm 0.9 - Particle size μm 43 - Density gr/cm^3 1.20

Physical and mechanical characteristics of the finished product: Density of the sintered product gr/cm^3 6.08 - Flexural strength MPa 1200 Fracture strength $MPa m^{0.5}$ 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^2/g 10 - e-modul 200 - Sintering temperature 1,530°C

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.oroDent.com website or request it directly at 045/6450635 or email sales@oroDent.com



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