

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

SRN: IT-MF-000030463

Device Name: Orodent

Model: Lux

Product Code: ZS98XXUMSY

CND (EMDN): Q010699

UDI-BASE: 805415427DZIRC02JX

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, Regulation 5, third indent, from Annex VIII of the Medical Device Regulation MDR 2017/745

Composition%: ZrO₂ 89-91, Y₂O₃ 7-7.74 (± 0.20), HfO₂ <1.8-2, Al₂O₃ 0.05 (± 0.10), SiO₂ ≤ 0.002 , Fe₂O₃ ≤ 0.002 , Co₃O₂ ≤ 0.02 , Er₂O₃ ≤ 2

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.

Method of Use: Class 3 monolithic ceramic suitable for the creation of prostheses with partially or totally coated substructure to be used with CAD/CAM system

Limitations: EN ISO 6872(E) table 1. Suitable for single crowns, inlays and veneers.

Minimum Thickness: 0.6 mm

Physical characteristics of raw materials: Crystallite size nm 36 - Particle size μm 0.44 - Particle size μm 44 - Density gr/cm³ 1.20

Physical and mechanical characteristics of the finished product: Density of the sintered product gr/cm³ 6.07 - Flexural strength MPa 600 Fracture strength MPa 3.27 - Hardness (HV30) 1300 - CET (25°C – 100°C) K-1 10x10-6 - Aging μm 2 - Translucency 49%

L.O.I. wt% 4 - BET m²/g 10 – 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)

UDI-BASE: 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 dent.com website or request it directly at 045/6450635 or email sales@oro dent.com