The Manufacturer: ORODENT S.R.L., Via M.G. Agnesi n.8, 37014, Castelnuovo del Garda (Verona)

SRN: IT-MF-000030463

GMN Code: 805415427

Declare that the product: ORODENT Zirconia for dental use

Trade Name: ORODENT EOS, ORODENT THOR, ORODENT VENUS, ORODENT GOLD, ORODENT WHITE MATT, ORODENT HIGH TRANSLUCENT, ORODENT PRESHADED, ORODENT BLEACH

COMMERCIAL NAME MODEL NUMBER (#)	REF	UDI-DI Basic
Orodent Venus	ZR98XXUMSYY	W805267989DZIRC0126
Orodent Thor	ZR98XXMSTYY	
Orodent Eos	ZR98XXMSYY	
Orodent Preshaded	ZR98XXTYY	
Orodent High Traslucent	ZR98XXT	
Orodent White Matt	ZR98XXH	
Orodent Bleach	ZR98XXT4	
Orodent Gold	ZR98XXG1200	

Risk class: IIa, rule 5, third -, by Annex VIII of the Medical Device Regulation MDR 2017/745.

Intended use: The ORODENT medical device consists of Zirconia for dental use and is intended for the production of prosthetic products suitable for restoring the functionality and aesthetics of the masticatory system, through mechanical processing. The ORODENT medical device is indicated for the restoration of single teeth in the anterior and posterior regions or bridges in case of partial edentulism in the anterior and posterior regions.

Certificate Number XXXXXXXX

Issued by NOTIFIED BODY:

IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.

Via Quintiliano, 43 20138 – MILANO – Italia

Notified Body number: 0051

The medical devices covered by the present EU declaration are in conformity with the (EU) MDR 2017/745 and with the following standars:

ISO 13485:2021 - Medical Devices: Quality managment system for regulatory purpose

ISO 14971:2019 - Medical Devices: Application of risk management to medical devices

ISO 10993-1:2021 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for

irritation and skin sensitization

ISO 15223-1:2021 - Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

ISO 20471:2021 - Medical devices — Information to be supplied by the manufacturer

No common specification is available for the medical devices covered by this declaration of conformity

The medical devices, covered by this declaration of conformity,

- do not incorporate, as an integral part, endocrine-disrupting substances, including phthalates, in accordance with points 10.4.1, 10.4.2 and 10.4.3 of Annex I of MDR 2017/745.
- do not incorporate, as an integral part, nanomaterials in accordance with points 10.6 of Annex I of MDR 2017/745
- do not incorporate, as an integral part, medicinal substances in accordance with point 12 of Annex I of MDR 2017/745.
- do not incorporate, as an integral part, tissues or cells of human origin or their derivatives, in accordance with point 13.1. of Annex I of MDR 2017/745.
- do not incorporate, as an integral part, tissues or cells of animal origin or their derivatives, in accordance with point 13.2. of Annex I of MDR 2017/745.

This declaration of conformity is issued under the sole responsibility of the manufacturer Orodent srl

Signed by:

Gaetano Gambini

Legal Representative

Castelnuovo del Garda, DD/MM/AAAA