

## CERTIFICATE

Certificat - Certificado- Сертификат - Zertifikat - 證書

- 1) **APPLICANT:** (who finally puts the product on the market)

OSAKADENT GROUP LIMITED

Guangdong Province, Foshan City, Jihua Road Number 13, Greenland Center, Two of the first floor, NO., P20

- 2) **CERTIFICATE NO.:** I/SETC.001620191219

**FILE REFERENCE:** CE-MDD-2019(A/0)

- 3) **ISET MARK:**



- 4) **CAUTION ABOUT CE MARKING** (Instruction for the Applicant who puts the product on the EU market):



The label of the CE Marking on the left side should be not less than 5mm height. CE Marking and EC Declaration of Conformity are duties for the manufacturer or its applicant who puts the product on the market. This one is responsible to start the CE marking and certification procedure as required by the legislation in force. Only for the products which are compulsorily included into specific Directives or Regulations will be necessary to appoint a Notified Body.

- 5) **TYPE OF PRODUCT:** Dental Unit, Dental Compressor, Curing Light, Oral camera, Dental Bur, Endo File

**MODEL(S):** See the following annex 1

- 6) **LIST OF DIRECTIVES / REGULATIONS / STANDARDS** (as declared by the manufacturer itself)

Medical Device Directive 93/42/EEC

EN ISO 14971:2012, EN ISO15223-1:2016, EN 1041:2008,

EN 60601-1:2006/AC:2010, EN 60601-1-2:2007/AC:2010, EN 1640:2010

- 7) **NOTE:** The applicant is aware about the contents and information included in the ModCOM04.06 Regulation for this type of Certificate that is considered totally accepted. The latest revision of the Regulation is available and can be downloaded from the website [www.iset-italia.eu](http://www.iset-italia.eu). This document is not referred to any evaluation that could be considered as included in the scope of the activities covered by the standard BS EN ISO/IEC 17065:2012 or European Regulation 765/2008.

- 8) **REMARK:** Certificate is issued on voluntary application from the Client and it gives to the applicant the right to use and affix the ISET Mark (at point 3) on their products, even if it doesn't imply any assessment on the safety and compliance of the product. ISET declares that the only scope of the assessment is to verify the existence of the declaration issued by the manufacturer or an applicant under its own responsibilities.

- 9) **DATE OF ISSUE:** 19/02/2025

**EXPIRY DATE:** 18/02/2028

- 10) **SIGNATURE:** Li Zhang

(On behalf of the Legal representative)





**ISTITUTO SERVIZI  
EUROPEI TECNOLOGICI**

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Cap. soc. i.v.

Cod. Fisc. e P.IVA Reg. Imprese

REA

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€ 10.200,00

02 332 750 369

02 332 750 369

MN 0221098

## ANNEX I

Product Name	Type/ Size
Dental Unit	OSA-A3, OSA-A2, OSA-G3, OSA-1, OSA-4C, OSA-1-2018, OSA-1-2305, OSA-1-98A, OSA-1-68B, OSA-1-68A, OSA-1-28A, OSA-1-28A(New), OSA-A6800, OSA-A3600, OSA-A6600, OSA-32, OSA-26, OSA-26A, OSA-208A, OSA-208D, OSA-208C, OSA-208E, OSA-208Q1, OSA-208Q2, OSA-208Q3, OSA-208Q5, OSA-398AA, OSA-S5
Dental Compressor	OSA-F193-A, OSA-SD30-C, OSA-194, OSA-193, OSA-193-A, OSA-192, OSA-192-A, OSA-192-B, OSA-191-B, OSA-191-A, OSA-191-5, OSA-191-6,
Dental Scaler	OSA-SPA-01, OSA-F091KA, OSA-F090C, OSA-M7-LED, OSA-F298
Enodo Motor	OSA-E13-USA-LED light, OSA-E13-6A, OSA-E19, OSA-E13-5A, OSA-E13-1, OSA-E13-3A
Curing light	OSA-Q9, OSA-Q6, OSA-1S-A, OSA-1S-P, OSA-F077W, OSA-F686C2
Dental Bur	Diamond Bur, Carbide bur, Ceramic bur, Grinding Drill, Brushes, Polishing Disc, Polishing burs, Rubber Polisher, Ceramic grinder, Tungsten Bur
Micro Applicator	749001-B, OSA-N-5, OSA-W8-A2, OSA-DP1, 709033A, 709033B