

EC Declaration of Conformity

EC Directive 93/42/EEC Annex II, excluded clause 4

Full Quality Assurance System

Medical Devices

Registration No.: HD 60094554 0001

Report No.: 28106546 001

Manufacturer: PALTOP Advanced Dental Solutions Ltd.
5 Hashita Ind Park
30899 Caesarea
Israel

Scope: DENTAL IMPLANTS;
PROSTHETIC COMPONENTS;
DENTAL SURGICAL INSTRUMENTS.
(See the attachment for models and codes designation)

Date of Expiry: 11/06/2019

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5, of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

Pogliano Milanese (MI)

12/06/2014


B. Tuzza



TÜV Rheinland Italia S.r.l. - Via Mattei, 3 - 20010 - Pogliano Milanese (MI)
Accredited by Ministry of Health and by Ministry of Economic Development
with decree of January 9th 2013 (G.U. n. 32 February 7th 2013)

Notified under No. **1936** to the EC Commission



The CE marking may be used if all relevant and effective EC Directives are complied with



TÜV Rheinland Italia S.r.l.

Via Mattei, 3 - 20010 - Pogliano Milanese (MI)



**Attachment to
certificate:**

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TÜV Rheinland Italia S.r.l.

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Types:

Medical Devices:

Dental implants

Model:

**Advanced implant
Dynamic implant**

Codes:

XX-YYYYY

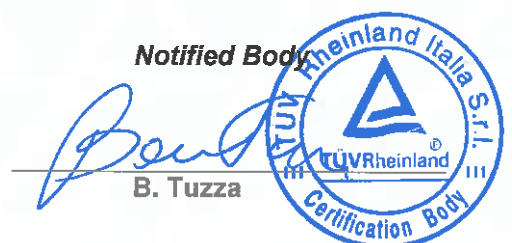
Legend:

XX: numbers that indicate the product group

YYYYY: progressive number

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Medical Devices

Prosthetic components

Model

Straight abutment

Angulated abutments

Anatomic angulated abutments

Straight ball abutment

Angulated 17° ball abutment

Multi unit abutment

Multi Unit Gold base abutment

Angulated Multi unit implant abutment

Codes

XX-YYYYY

Legend

XX: numbers that indicate the product group

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Medical Devices

Prosthetic components

Model:

Healing cap

Healing cap for Single Unit

Healing cap for Multi Unit

UNF 1-72 Direct screw

Multi unit screw UNF 1-72

Direct screw Narrow

Straight abutment Zirconia

Angulated abutment Zirconia

Anatomic angulated abutment Zirconia

Straight anatomic concave abutment

Anatomic angulated concave abutment

Wide cover screw

Single unit abutment

Base Abutment For Technician

Single unit abutment

Passive abutment

Blank abutment

Codes:

XX-YYYYY

Legend:

XX: numbers that indicate the product group

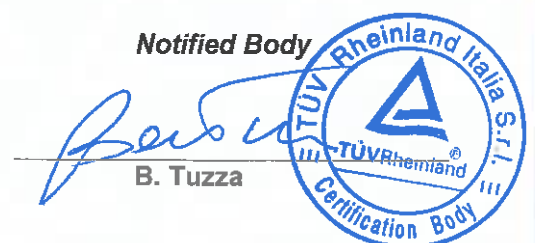
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Medical Devices:

Dental surgical instruments

Model:

Long step drill
Short step drill
Pilot drill (spade)
Round bur
Implant long final drill
Implant short final drill
Drill extender
Small surgical box
Large surgical box
Large complete surgical box
Osteotome
Access bone remover drill
Drill stop kit

Codes:

XX-YYYYY


Key:

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