

Declaration of Conformity

Alphadent NV
Mannebeekstraat 33
8790 Waregem, Belgium

Hereby we declare that the Alphadent NV as legal manufacturer has the exclusive responsibility to draw up this Declaration of Conformity.

This declaration concerns the following products:

1100/H/ZR/OR	PRECI-BAR STD. RIDER OR
1102/H/ZR/OR	PRECI-BAR MINI RIDER OR
1105/B	PRECI-CLIP PROFILE OR 5 CM
1109/B	PRECI-CLIP PROFILE LASER TI 5 CM
1125	PRECI-CLIP RIDER OR OC + SM. 2 PCS
1125AB	PRECI-CLIP RIDER OR OC + SP. MAIN 20 PCS
1126	PRECI-CLIP RIDER INOX OC + SM 2 PCS
1126AB	PRECI-CLIP RIDER INOX OC + SM 20 PCS
1201	PRECI-BALL STD OR/OR
1201 A	PRECI-BALL FEMALE STD OR
1201 AB	PRECI-BALL FEMALE OR 20 PCS
1201 B	PRECI-BALL SM PVC
1201 C	PRECI-BALL MALE OR
1203	PRECI BALL TI/PA
1203 C	PRECI-BALL MALE PA
1205	PRECI-BALL PC TI/PL
1205 A	PRECI-BALL FEMALE TI
1205 AB	PRECI-BALL FEMALE TI 20 PCS
1206	PRECI-BALL CV OR/TI
1206 C	PRECI-BALL/CLIX MALE V
1206 CL	PRECI-BALL/CLIX PATRIX V LONG
1207	PRECI-BALL AVK TI/PA
1207 A	PRECI-BALL FEMALE V
1207 A / 2,15	PRECI-BALL V 2.15 MM
1209	PRECI-BALL STD OR/IR
1209 C	PRECI-BALL MALE IR
1226	PRECI-CLIX R BURR SET 3 PCS
1227	PRECI-CLIX PREDRILLING BURR



1228	PRECI-CLIX CAVITY BURR
1229	PRECI-CLIX PRECISION REAMER
1231	PRECI-CLIX FEMALE YELLOW 6 PCS
1231B	PRECI-CLIX FEM. YELLOW 50 PCS
1232	PRECI-CLIX FEMALE WHITE 6 PCS
1232B	PRECI-CLIX FEMALE WHITE 50 PCS
1233	PRECI-CLIX FEMALE RED 6 PCS
1233B	PRECI-CLIX FEMALE RED 50 PCS
1234	PRECI-CLIX FEMALE COMBI 2+2+2
1235	PRECI-CLIX HOUSING 6 PCS
1235B	PRECI-CLIX HOUSING 50 PCS
1242	PRECI-CLIX FEMALE SET
1242 S	PRECI-CLIX FEMALE INTRO SET
1251	PRECI-CLIX ATI
1251 S	PRECI-CLIX SET LAB KIT ATI
1252	PRECI-CLIX AP
1256	PRECI-CLIX CC
1257	PRECI-CLIX CP
1261	PRECI-CLIX CV
1261 S	PRECI-CLIX SET LAB KIT CV
1271	PRECI-CLIX TI-TI
1271 C	PRECI-CLIX MALE TI
1271 S	PRECI-CLIX SET LAB KIT T-TI
1272	PRECI-CLIX P-TI
1276	PRECI-CLIX TI-V
1276 S	PRECI-CLIX SET LAB KIT TI-V
1277	PRECI-CLIX P-V
1281	PRECI-CLIX TI-PL
1281 S	PRECI-CLIX SET LAB KIT TI-P
1282	PRECI-CLIX PL-PL
1291	PRECI-CLIX RTI
1291 C	PRECI-CLIX CANAL POST
1292	PRECI-CLIX RP
1293	PRECI-CLIX RCT
1293 C	PRECI-CLIX C POST
1294	PRECI-CLIX RCP
1297	PRECI-CLIX RC SET DENTIST
1299	PRECI-CLIX SET DENTIST
1301	PRECI-SAGIX INTRO SET P
1303	PRECI-SAGIX INTRO SET M
1311	PRECI-SAGIX 1,7 FEMALE YELLOW 6 PCS
1311B	PRECI-SAGIX 1,7 FEMALE YELLOW 50 PCS
1312	PRECI-SAGIX 1,7 FEMALE WHITE 6 PCS



1312B	PRECI-SAGIX 1,7 FEMALE WHITE 50 PCS
1313	PRECI-SAGIX 1,7 FEMALE RED 6 PCS
1313B	PRECI-SAGIX 1,7 FEMALE RED 50 PCS
1314	PRECI-SAGIX 1,7 FEMALE 2+2+2 PCS
1322	PRECI-SAGIX 1,7 MALE M 2 PCS
1322B	PRECI-SAGIX 1,7 MALE M 20 PCS
1325	PRECI-SAGIX 1,7 HOUSING 2 PCS
1325B	PRECI-SAGIX 1,7 HOUSING 20 PCS
1351	PRECI-SAGIX SET 1,7 PH
1352	PRECI-SAGIX SET 1,7 MH
1356	PRECI-SAGIX SET 2,2 PH
1357	PRECI-SAGIX SET 2,2 MH
1361	PRECI-SAGIX 2.2 FEMALE YELLOW 6 PCS
1361B	PRECI-SAGIX 2,2 FEMALE YELLOW 50 PCS
1362	PRECI-SAGIX 2,2 FEMALE WHITE 6 PCS
1362B	PRECI-SAGIX 2,2 FEMALE WHITE 50 PCS
1363	PRECI-SAGIX 2.2 FEMALE RED 6 PCS
1363B	PRECI-SAGIX 2,2 FEMALE RED 50 PCS
1364	PRECI-SAGIX 2,2 FEMALE 2+2+2 PCS
1372	PRECI-SAGIX 2,2 MALE M 2 PCS
1372B	PRECI-SAGIX 2,2 MALE M 20 PCS
1373	PRECI-SAGIX 2,2 MALE V 1 P.
1374	PRECI-SAGIX 2,2 MALE VCC 1 P.
1375	PRECI-SAGIX 2.2 HOUSING 2 PCS
1375B	PRECI-SAGIX 2.2 HOUSING 20 PCS
1391	PRECI-SAGIX FEMALE 1.7 INTRO 13 PCS
1392	PRECI-SAGIX FEMALE 2.2 INTRO 13 PCS
1393	PRECI-SAGIX FEMALE 1.7&2.2 INTRO 25 PCS
1551	PRECI-52 U
1556	PRECI-52 S
1561	PRECI-52 U FEMALE PLASTIC 2 PCS
1563	PRECI-52 U INTERNAL MALE SET 2 PCS
1564	PRECI-52 PROCESSING PLUG 6 PCS
1566	PRECI-52 S FEMALE PLASTIC 2 PCS
1568	PRECI-52 S INTERNAL MALE SET 2 PCS
1701	PRECI-HORIX STD SET
1706	PRECI-HORIX HOUSING 6 PCS
1706B	PRECI-HORIX HOUSING 50 PCS
1731	PRECI-HORIX PW SET
1737	PRECI-HORIX SERVICE SET
1741	PRECI-HORIX COMBI
1742	PRECI-HORIX COMBI CKMX
1801	PRECI-VERTIX STD SET



1802	PRECI-VERTIX/HORIX FEMALE YELLOW 6 PCS
1802B	PRECI-VERTIX/HORIX YELLOW 50 PCS
1805	PRECI-VERTIX/HORIX WHITE 6 PCS
1805B	PRECI-VERTIX/HORIX WHITE 50 PCS
1806	PRECI-VERTIX/HORIX RED 6 PCS
1806B	PRECI-VERTIX/HORIX RED 50 PCS
1807	PRECI-VERTIX/HORIX MIX 2+2+2
1807B	PRECI-VERTIX/HORIX MIX 25+15+10
1811	PRECI-VERTIX P SET
1812	PRECI-VERTIX P COMBI SET
1822	PRECI-VERTIX AT FRICTION 6 PCS
2001	PRECI-POST SET
2004B	PRECI-POST REAMER BLUE
2004G	PRECI-POST REAMER YELLOW
2951A	PRECI-POST CC REAMER A
2952B	PRECI-POST CC REAMER B
2953C	PRECI-POST CC REAMER C
2954D	PRECI-POST CC REAMER D
334 A	RETENTION NUT TI
334 C	CEKA SPRING PIN
334 C / 195	CEKA SPEC. SPRING PIN 1.95 MM 2 PCS
334 C / 202	CEKA SPEC. SPRING PIN 2.02 MM 2 PCS
444 C	CEKA SPRING PIN
5 CS	CEKA SPRING PIN
6700	CEKA Multi SET
6701	CEKA Multi COMPOSITE
6702	CEKA Multi PRIMER
6710	CEKA Multi SET O
6711	CEKA Multi COMPOSITE O
691 A	CEKA M3 AXIAL FEMALE TI
691 D	CEKA M3 AXIAL BASE RING PA
691 TI	CEKA M3 AXIAL TI/PA
693	CEKA M3 AXIAL IR/IR
693 A	CEKA M3 AXIAL FEMALE IR
693 D	CEKA M3 AXIAL BASE RING IR
693 TI	CEKA M3 AXIAL TI/IR
694 AKS	CEKA M3 RET. PART ACRYLIC 2 PCS
694 AKS2	CEKA M3 RET. PART ACRYLIC 2 PCS
694 AL	CEKA M3 RETENTION PART LASER 2 PCS
694 AR	CEKA M3 RETENTION PART SPACER 2 PCS
694 AS	CEKA M3 RET. PART SOLDERING PA 2 PCS
694 C	CEKA M3 SPRING PIN RESIL. PA 2 PCS
694 C / 195	CEKA M3 SPEC SPRING PIN 1.95 MM 2 PCS

694 C / 202	CEKA M3 SPEC SPRING PIN 2.02 MM 2 PCS
694 C / 209	CEKA M3 SPEC SPRING PIN 2.09 MM 2 PCS
694 C/L	CEKA M3 SPEC. SPRING PIN LONG 2 PCS
694 TI	CEKA M3 FEMALE TI 2 PCS
724 C	CEKA M3 SPRING PIN RIGID PA 2 PCS
724 C / 195	CEKA M3 SPEC SPRING PIN 1.95 MM 2 PCS
724 C / 202	CEKA M3 SPEC SPRING PIN 2.02 MM 2 PCS
724 C / 209	CEKA M3 SPEC SPRING PIN 2.09 MM 2 PCS
724 CX	CEKA M3 SPRING PIN OLD TYPE
AF 69	SPACER DISC 0.05 MM 10 PCS
CEKA SITE	CEKA SITE SET 2 x 2 GR
CS00	* CEKA SOL
CS00 F	* CEKA SOL FILIGRAN
CS20	* CEKA SOL G
CS21	* CEKA SOL L
CS22	* CEKA SOL W
CS23	* CEKA SOL CR
CS31	CEKA SOL TI
IMP-CK-015	STRAIGHT PROFILE LASER 50 MM
IMP-CK-016	CURVED PROFILE LASER 50 MM
IMP-CK-025	STRAIGHT PROFILE LASER 25 X 50 MM
IMP-CK-026	CURVED PROFILE LASER 25 X 50 MM
OL 0200 IR	REVAX M3 FEMALE IR (3+1)
OL 0200 TI	REVAX M3 FEMALE TI (3+1)
OL 0261 IR	REVAX M3 IR/SOLDERING
OL 0261 TI	REVAX M3 TI/SOLDERING
OL 0265 TI	REVAX M3 TI/LASER
OL 0275 IR	REVAX M3 IR/ACRYLIC
OL 0275 TI	REVAX M3 TI/ACRYLIC
OL 0285 IR	REVAX M3 IR/SPACER
OL 0285 TI	REVAX M3 TI/SPACER
OL 0295 IR	REVAX M3 IR/ACRYLIC
OL 0295 TI	REVAX M3 TI/ACRYLIC
OL 0800 TI	REVAX M3 FEMALE 0° TI (1+1)
OL 0885 TI	REVAX M3 AXIAL TI/SPACER
OL 0895 TI	REVAX M3 AXIAL TI/ACRYLIC
OL 334	CEKA M3 IR
OL 5 SPR	CEKA M3 PR
OL 694 D	CEKA M3 FEMALE IR
OL 694 DPR	CEKA M3 FEMALE PR
OL 694 KS	CEKA M3 IR/ACRYLIC
OL 694 KSPR	CEKA M3 PR/ACRYLIC
OL 694 R	CEKA M3 IR/SPACER



OL 694 RPR	CEKA M3 PR/SPACER
OL 694 S	CEKA M3 IR/SOLDERING
OL 694 SPR	CEKA M3 PR/SOLDERING
OL 724 KS	CEKA M3 IR/ACRYLIC
OL 724 KSPR	CEKA M3 PR/ACRYLIC
OL 724 R	CEKA M3 IR/SPACER
OL 724 RPR	CEKA M3 PR/SPACER
OL 724 S	CEKA M3 IR/SOLDERING
OL 724 SPR	CEKA M3 PR/SOLDERING
PRECI 2	PROMO KIT PRECI 2
PRECI 3	PROMO KIT PRECI 3
PROMO PSAG 01	PRECI-SAGIX PROMO 01
PROMO PSAG 02	PRECI-SAGIX PROMO 02
PROMO PSAG 03	PRECI-SAGIX PROMO 03
PROMO PSAG 10	PRECI-SAGIX PROMO 10
PROMO PSAG 11	PRECI-SAGIX PROMO 11
RA 0061	REVAX M2 BASE RING PA
RA 0063	REVAX M2 BASE RING IR
RA 0091	REVAX M2 AXIAL FEMALE TI
RA 0093	REVAX M2 AXIAL FEMALE IR
RA 61 TI	REVAX M2 AXIAL TI/PA
RA 63 TI	REVAX M2 AXIAL TI/IR
RA AX63	REVAX M2 AXIAL IR/IR
RE 0031	REVAX M2 SPRING PIN + SPACE M. 2 PCS
RE 0031 195	REVAX M2 SPEC. SPR. PIN 1.95MM 2 PCS
RE 0031 202	REVAX M2 SPEC. SPR. PIN 2.02 MM 2 PCS
RE 0031 L	REVAX M2 SPEC. SPRING PIN LONG 2 PCS
RE 0061	REVAX M2 RET.PART SOLDERING PA 2 PCS
RE 0065	REVAX M2 RET.PART LASER TI 2 PCS
RE 0075	REVAX M2 RET.PART ACRYLIC TI 2 PCS
RE 0085	REVAX M2 RET.PART SPACER TI 2 PCS
RE 0095	REVAX M2 RET.PART ACRYLIC TI 2 PCS
RE 0100 IR	REVAX M2 FEMALE IR (3+1)
RE 0100 TI	REVAX M2 FEMALE TI (3+1)
RE 0161 IR	REVAX M2 IR/SOLDERING
RE 0161 TI	REVAX M2 TI/SOLDERING
RE 0175 IR	REVAX M2 IR/ACRYLIC
RE 0175 TI	REVAX M2 TI/ACRYLIC
RE 0185 IR	REVAX M2 IR/SPACER
RE 0185 TI	REVAX M2 TI/SPACER
RE 0195 IR	REVAX M2 IR/ACRYLIC
RE 0195 TI	REVAX M2 TI/ACRYLIC
RE 0700 TI	REVAX M2 AXIAL FEMALE TI (1+1)



RE 0761 TI	REVAX M2 AXIAL TI/SOLDERING
RE 0785 TI	REVAX M2 AXIAL TI/SPACER
RE 0795 TI	REVAX M2 AXIAL TI/ACRYLIC
RE 4500 TI	REVAX M2 FEMALE TI 2 PCS
RE 4600 TI	PRECI-CLIX THREADS TI
REVAX LK 3	LABORATORY KIT
REVAX OK 2	DENTIST KIT
REVAX SP 1	SPRING PIN KIT M2 & M3
REVAX SP 2	SPRING PIN KIT M2
REVAX SP 3	SPRING PIN KIT M3
SA 601	SAPHIR FEMALE TI
SA 603	SAPHIR SPRING PIN 2 PCS
1100/B/OR	PRECI-BAR STD. U-PROFILE OR 5 CM
1100/B/PA	PRECI-BAR STD. U-PROFILE OR 5 CM
1100/BL/OR	PRECI-BAR STD. U-PROFILE OR 20 CM
1100/BL/PA	PRECI-BAR STD. U-PROFILE PA 20 CM
1100/H/MR/IN	PRECI-BAR STD. RIDER IN + SM 5 CM
1100/H/MR/OR	PRECI-BAR STD. RIDER OR + SM 5 CM
1100/H/MR/PA	PRECI-BAR STD. RIDER PA + SM 5 CM
1100/H/ZR/PA	PRECI-BAR STD. RIDER OR
1101/B/OR	PRECI-BAR STD. OV-PROFILE OR 5 CM
1101/B/PA	PRECI-BAR STD. OV-PROFILE OR 5 CM
1101/BL/OR	PRECI-BAR STD. OV-PROFILE OR 20 CM
1101/BL/PA	PRECI-BAR STD. OV-PROFILE PA 20 CM
1102/B/OR	PRECI-BAR MINI U-PROFILE OR 5 CM
1102/BL/OR	PRECI-BAR MINI U-PROFILE OR 20 CM
1102/H/MR/IN	PRECI-BAR MINI RIDER IN + SM 5 CM
1102/H/MR/OR	PRECI-BAR MINI RIDER OR + SM 5 CM
1102/H/MR/PA	PRECI-BAR MINI RIDER PA + SM 5 CM
1102/H/ZR/PA	PRECI-BAR MINI RIDER OR
1103/B/OR	PRECI-BAR MINI OV-PROFILE OR 5 CM
1103/B/PA	PRECI-BAR MINI OV-PROFILE OR 5 CM
1103/BL/OR	PRECI-BAR MINI OV-PROFILE OR 20 CM
1103/BL/PA	PRECI-BAR MINI OV-PROFILE PA 20 CM
1601	PERMA-RET SET
1602	PERMA-RET WIRE 1M

which are Class II a medical devices under article 10, § 1 KB 18/03/1999 and rule 5 of the Annex IX of the medical device directive 93/42/EEC.

Alphadent NV declares that these products are in conformity with the essential requirements and provisions of the Medical Device Directive 93/42/EEC, Annex II.



Alphadent NV has a Quality System in place based on EN ISO 13485:2012 for product development, production and distribution of these medical devices.

The following specific product related standards are applied:

EN 1639:2009

Dentistry - Medical devices for dentistry - Instruments

EN 1640:2009

Dentistry - Medical devices for dentistry - Equipment

EN 1641:2009

Dentistry - Medical devices for dentistry - Materials

EN ISO 10993-1:2009

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

EN ISO 10993-5:2009

Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

EN ISO 10993-10:2013

Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

ISO 22674:2016

Dentistry – Metallic materials for fixed and removable restorations and appliances

This Declaration of Conformity is valid for all devices described here above and until the issue of a revised Declaration of Conformity after change of the product and/or by the expiration date of the certificate(s) issued by the Notified Body.

Name and address of the Notified Body involved in the conformity assessment procedure:

TÜV Rheinland LGA Products GmbH

Tillystr. 2

90431 Nürnberg

Notified Body Registration Nr. 0197.

Waregem, 20-12-2017



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