



**ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.**

**NATIONAL EVALUATION CENTER
OF QUALITY & TECHNOLOGY
IN HEALTH S.A.**

EC CERTIFICATE FULL QUALITY ASSURANCE SYSTEM

We hereby certify that the under mentioned manufacturer has established and maintains a full quality assurance system according to the requirements of Directive 93/42/EEC, Annex II (with the exemption of section 4) and its transposition in Greek legislation, for the design, manufacture and final inspection of the products mentioned in this certificate.

The certificate is subject to terms and conditions overleaf.

Any significant changes in design or manufacture may render this certificate invalid.

Certificate Number: 301041498

Manufacturer: TEHNODENT Co LTD

Facility: 1/6 BERYOZOVAYA STR., SEVERNYI, BELGOROD REGION, RUSSIA.

Products:

- 1. GLASS IONOMER & POLYMER BASED DENTAL MATERIALS
- 2. DENTAL ADHESIVES
- 3. DENTAL ETCHANTS
- 4. DENTAL MATERIALS FOR GINGIVAL RETRACTION AND HEMOSTASIS
- 5. ROOT CANAL'S FILLING DENTAL MATERIALS
- 6. ANTISEPTIC DENTAL MATERIAL FOR HARD TOOTH TISSUES
- 7. EDTA SOLUTIONS
- 8. FINAL VARNISH
- 9. DENTIN CONDITIONER

Devices Classification:

- 1. 2. 3. 4. 7. 8. 9: IIa
- 5.1: IIa, 5.2: IIa, 5.3: IIa, 5.4: IIb, 5.5: IIa
- 6: III

Current issue date 24/05/2021

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Audit report: 200031498


ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFThERIA, President & Managing Director

Το Εθνικό Κέντρο Αξιολόγησης της Ποιότητας και Τεχνολογίας στην Υγεία (ΕΚΑΠΤΥ) είναι Κοινοποιημένος Οργανισμός σύμφωνα με την Οδηγία 93/42/ΕΟΚ περί των ιατροτεχνολογικών προϊόντων, με αριθμό αναγνώρισης 0653.

National Evaluation Center of Quality & Technology In Health S.A. (EKAPTY) is a Notified body according to Council Directive 93/42/EEC concerning medical devices, with identification number 0653.



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ANNEX NO. 301041498 CERTIFICATE

DENTAL MEDICAL DEVICES	COMMERCIAL NAMES
1. GLASS IONOMER & POLYMER BASED DENTAL MATERIALS	1.1 GLASSYCEM RADIOPAQUE GLASS IONOMER LUTING CEMENT (POWDER-LIQUID) 1.2 GLASSYCEM RADIOPAQUE GLASS IONOMER RESTORATIVE CEMENT (POWDER- LIQUID) 1.3 GLASSYCEM FOR KIDS RADIOPAQUE GLASS IONOMER RESTORATIVE CEMENT (POWDER-LIQUID) 1.4 RELIGHT UNIVERSAL LIGHT-CURING RESTORATIVE COMPOSITE 1.5 RELIGHT COLOUR LIGHT-CURING COLOUR 1.6 RELIGHT FLOW LIGHT-CURING FLOWABLE COMPOSITE 1.7 RELIGHT TEMPO LIGHT-CURING TEMPORARY FILLING COMPOSITE 1.8 RELIGHT TEMPO LIGHT-CURING FLOWABLE TEMPORARY FILLING COMPOSITE 1.9 RELIGHT KIT - UNIVERSAL LIGHT-CURING RESTORATIVE COMPOSITE KIT (8 SYRINGES/ 6 SYRINGES/ 4 SYRINGES)
2. DENTAL ADHESIVES	2.1 RELIGHT BOND LIGHT-CURING SINGLE-COMPONENT BONDING AGENT
3. DENTAL ETCHANTS	3.1. TH GEL FOR ETCHING
4. DENTAL MATERIALS FOR GINGIVAL RETRACTION AND HEMOSTASIS	4.1 HEMOSTOP LIQUID FOR GINGIVAL RETRACTION AND HEMOSTASIS 4.2 HEMOSTOP GEL FOR GINGIVAL RETRACTION AND HEMOSTASIS
5. ROOT CANAL'S FILLING DENTAL MATERIALS	5.1 EPOXIDIN ROOT CANALS SEALER BASED ON EPOXY RESIN 5.2 EPOXIDIN DUO ROOT CANALS SEALER BASED ON EPOXY RESIN 5.3 ROOTDENT ROOT CANAL REPAIR PRODUCT (POWDER OR QUICK-HARDENING POWDER) 5.4 EUGETIN ZINC OXIDE-EUGENOL CEMENT FOR ROOT CANAL SEALING 5.5 CALCETIN ENDO CALCIUM HYDROXIDE-BASED PRODUCT FOR ROOT CANAL SEALING
6. ANTISEPTIC DENTAL MATERIAL FOR HARD TOOTH TISSUES	6.1 CRESOTIN LIQUID No 2 FOR ANTISEPTIC OF TOOTH ROOT CANALS
7. EDTA SOLUTIONS	7.1 EDETECT LIQUID 7.2 EDETECT GEL 7.3 EDETECT GEL WITH PEROXIDE
8. FINAL VARNISH	8.1 GLASSYCEM FINAL VARNISH
9. DENTIN CONDITIONER	9.1 GLASSYCEM CONDITIONER

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TERMS & CONDITIONS

1. For class I sterile products, the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions.
2. For Class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.
3. For class III products an additional Design Examination certificate is required according to the requirements of Annex II 93/42/EEC (section 4).
4. The certificate is valid only for the products and the facilities mentioned.
5. Periodical surveillance as referred in 93/42/EEC will be held in order to verify that the manufacturer maintains and applies the quality system.
6. When meeting with the terms and conditions above, the manufacturer may draw up an EC declaration of conformity and legally affix the CE 0653 mark.



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