

EVPÚ

NOTIFIED BODY No. 1293

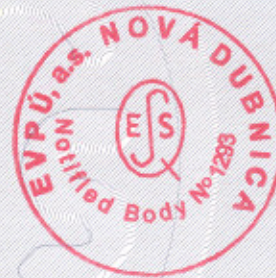
EC CERTIFICATE PRODUCTION QUALITY ASSURANCE

Directive 93/42/EEC on Medical devices, Annex V,
transposed into "Slovak government decree No. 572/2001 Coll. of Laws" as amended

No. 43082/101/1/2008/CE

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.. Identification of the products covered by this certificate is given in the Appendix.

Manufacturer and Facility	Amrit Chemical & Minerals Agency F-343, Phase – VIII-B, Industrial Area, Mohali-160071, Chandigarh India
Applicant	Amrit Chemical & Minerals Agency F-343, Phase – VIII-B, Industrial Area, Mohali-160071, Chandigarh India
Product(s)	Endodontic Material; Filling Material; Preventive material; Miscellaneous material
Product type(s)	see Annex 1
Classification of medical device	MD Directive 93/42/EEC – Class IIa
Scope of quality system	Production
Final report number	43082/2008/C
Date of issue	March 14, 2008
Date of the end of validity	March 13, 2013



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Marking may only be used if all relevant and effective Directives of EP and Council are complied with.

The Notified Body has audited the quality system in accordance with the Directive 93/42/EEC Annex V (3) and found that the quality system meets the requirements in the Directive 93/42/EEC Annex V.

The placing on the market of Class IIb and Class III devices covered by this certificate an EC type-examination certificate according to the Directive 93/42/EEC Annex III is required.

The manufacturer must inform EVPÚ a.s. of any plan for substantial changes in the design, construction of the products or the quality system of production in order to examine whether this Certificate remains valid. Annual Surveillance Audits will be held to verify the validity of this Certificate.

This Certificate is valid until the date specified. Any significant changes in the design or construction of the products, the quality system or amendments to the Directive 93/42/EEC may render this Certificate invalid at an earlier date. The product liability rests with the manufacturer or his representative in accordance with the Directive 85/374/EEC.

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EVPÚ a.s., NB No. 1293, Trenčianska 19, 018 51 Nová Dubnica, Slovak Republic

Annex 1 to EC CERTIFICATE No. 43082/2008/C from March 14, 2008:

Product Type	Product Name	Brand	GMDN Code
Endodontic Material	Calcium hydroxide paste	CalExcel	16182
	Calcium Hydroxide with Iodoform paste	Calform RC	16182
	Light Cure calcium Hydroxide paste	LC CalExcel	16182
	Root canal Preparation Gel With EDTA and Carbamide Peroxide	Prep Canal	39212
	17% diSodium Edetate Solution	Canalarge	38996
	Root Canal filling remover	Canalsolve	34527, 33538
	10% Citric acid solution	Citocid	39897
	2% Chlorhexidene sol.	Dentochlor	17611
	Pulp Devitalizing paste	D-Pulp	37242, 39170
	Dehydrating and degreasing agent	Dryon/Dhydral	33615, 41689
	Disinfectant solution for root canal	Cresolve	37518, 42878
	Disinfectant solution for Pulp	Pulpol	37518
	Sodium Hypochlorite	----	37259, 30193
Filling Material	Type II Glass Ionomer Cement	GI fil	38766
	Type I Glass Ionomer Cement	GI Luting	38766
	Root Canal Filling Material	Resinoseal	34780
	Root Canal Filling Material	Endoflux	34780
	Root Canal Filling Material	Endoflux-Ne	34780
	Resin Bonded Zinc Oxide Eugenol Cement	Zinogen	34778
	Temporary Filling pastes non-Eugenol	Cavitemp	34787
	Zinc Oxide	----	34787
	Eugenol	----	31896
	Mercury	----	35767
	Zinc Phosphate Cement	----	34775
	Poly Carboxylate Cement	----	34777, 16705
	Composite Filling Material	LC fill	39174, 16707
	Bonding Agent- Dentine Enamel	----	34782, 37442
	Self Etching Bonding	----	36153
Preventive Material	Desensitizing gel with 1.1% Sodium Fluoride (Neutral Gel)	DSENSE	42341
	2% Sodium Fluoride	Fluorosolve	42341
Miscellaneous	Tooth whitening gel containing 10%, 16%, 22% and 35% Carbamide Peroxide	Ultrawhite	39212
	Prophylaxis paste containing Pumice	Prolax	16184, 35768
	Sticky Wax Green stick	----	16427
	Etching gel contains 37% Phosphoric acid	Frost	31400
	Cavity varnish	Cavlaq/Provar	16183
	Calcium hydroxide powder	----	39201
	20% Ferric Sulfate haemostatic gel	Easy stat	40173, 31387
Caries detecting dye	----	33995	



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