



EVPŮ[®]

NOTIFIED BODY No. 1293

EC CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical devices, Annex II (with the exemption of section 4), transposed into "Slovak government decree No. 572/2001 Coll. of Laws" as amended

No. 40030/101/1/2010/CE

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive. Identification of the products covered by this certificate is given in the Appendix.

Manufacturer and Facility	UAB "Medicinos linija" Karaliauciaus str. 29, LT-78374 Siauliai, Lithuania
Applicant	UAB "Medicinos linija" Karaliauciaus str. 29, LT-78374 Siauliai, Lithuania
Product(s)	Light Cure composite, Chemical Cure composite, Etchants Bonding Adhesive, Temporary materials, Cements
Product type(s)	see Annex 1
Classification of medical device	Medical Devices – Class IIa
Scope of quality system	Quality of design, production, storage and distribution of dental materials
Final report number	40030/2010/C
Date of issue	March 18th, 2010
Date of the end of validity	March 17th, 2015



Karol Glamoš



The 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 II (3) and found that the quality system meet the requirements of the Directive 93/42/EEC Annex II.

The placing on the market of Class III devices covered by this certificate an EC design-examination certificate according to the Directive 93/42/EEC Annex II (4) is required.

The manufacturer must inform EVPŮ 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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