EVPÚ

NOTIFIED BODY No. 1293

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, as amended by 2007/47/EC of the European Parliament and of the Council (MDD), Annex II excluding (4) (*Module H*), transposed into "Slovak government decree No. 552/2008 Collection of Laws" as amended

No. 43044/101/1/2015/CE

EVPÚ a.s., Notified Body No. 1293, has audited the quality system in accordance with MDD Annex II and found that the quality system meets the requirements of MDD Annex II.

Manufacturer and Facility	Medicinos linija, UAB, Karaliaučiaus St. 29, LT-78374 Siauliai, Lithuania
Device(s)	Dental materials
Type(s)	See Annex 1
Device(s) in	Class IIa
Relevant report(s) Audit report	43044/2015/C M020/10-5

Marek Hudák

Issued on July 15th, 2015 Valid until July 15th, 2020

Manufacturer can affix the CE mark with number of Notified Body only in case devices are in comply with all relevant and effective Directives of European Parliament and of the Council. Surveillance audits according to Annex II (6) will be held to verify the validity of this Certificate.

The manufacturer must inform EVPÚ a.s. of any plan for substantial changes in the design of the device(s), in construction of the device(s) or in the quality system of production in order to examine whether this Certificate remains valid.

This Certificate is valid until the date specified. Any sufficient changes in the design of the device(s), in construction of the device(s), in the quality system or amendments to the Directive 93/42/EEC, as amended by 2007/47/EC may render this Certificate invalid at an earlier date. The product liability rests with the manufacturer or his representative in accordance with the