

JSC «VLADMIVA» EXPERIMENTAL PLANT

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Russia



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EC DECLARATION OF CONFORMITY

Manufacture: JSC "Experimental Plant "VladMiVa"
Address: 19-Studencheskaya Str., Belgorod 308023, Russia
EC-Representative: UAB „Inoveca Medtechna“,
Director Kestutis Sirgedas
Verkiu str. 29, LT-09108,
Vilnius, Lithuania

Products: AUXILIARY DENTAL MATERIALS

Name	1) Moulding material for producing fire-proof models to be used when making denture frames using chromium-cobalt, silver-palladium and other precious alloys "Beloform" 2) Set of abrasive electrocorundum powders for grinding and polishing of dental metal products "Belect" 3) Separating dental varnish "Isalgin" 4) Set of liquids for processing dental impressions "Orthosol" (-Adhesive, -Dent, -Impres, -Cleans) 5) Dental liquid for whitening stainless steel products "Otbel" 6) Dental low-melting alloy for making dies and models dental low-melting alloy "VladMiVa" 7) Ceramic crucibles for fusing metals and alloys in furnace of induction heating 8) Set of gels for whitening, remineralizing and fluorinating of tooth enamel «Belagel» (-O 12,20,30%, -Ca/P, -R, -F, -O(Light), -O(Endo), -O(Active), -O(White)) 9) Dental fluorinating one-component anticaries analgetic varnish "Belak-F" (transparent)
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We hereby declare that the above mentioned products meet the provisions of European standards for safety performance. All supporting documentation is retained in the manufacturer's premises

European standards	➤ EN 1641:2009 Dentistry – Medical devices for dentistry – Materials ➤ EN ISO 10993-1:2003 - Medical devices. Biological evaluation of medical devices. Part 1. Evaluation and testing (ITD) ➤ EN ISO 10993-5:1999 - Medical devices. Biological evaluation of medical devices. Part 5. Tests for in vitro cytotoxicity (ITD) ➤ EN ISO 10993-10:2002 - Medical devices. Biological evaluation of medical devices. Part 10. Tests for irritation and delayed-type hypersensitivity (ITD)
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Place, Date of issue: Belgorod, 28.02.2017.

JSC "Experimental Plant "VladMiVa"

Name: V.P. Chusy

Position: General Director

Signature:



UAB „Inoveca Medtechna“

Name: K. Sirgedas

Position: Director

Signature:

