

## JSC «VLADMIVA» EXPERIMENTAL PLANT

Studencheskaya Str., 19  
Belgorod 308023  
Russia



Tel: +7(4722) 200-555,  
Fax: +7(4722) 31-59-03  
e-mail: [postmaster@vladmiva.ru](mailto:postmaster@vladmiva.ru)  
[www.vladmiva.ru](http://www.vladmiva.ru)

### 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”<br>2) Set of abrasive electrocorundum powders for grinding and polishing of dental metal products “Belect”<br>3) Separating dental varnish “Isalgin”<br>4) Set of liquids for processing dental impressions “Orthosol” (-Adhesive, -Dent, -Impres, -Cleans)<br>5) Dental liquid for whitening stainless steel products “Otbel”<br>6) Dental low-melting alloy for making dies and models dental low-melting alloy “VladMiVa”<br>7) Ceramic crucibles for fusing metals and alloys in furnace of induction heating<br>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))<br>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

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|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| European standards | <ul style="list-style-type: none"><li>➤ EN 1641:2009 Dentistry – Medical devices for dentistry – Materials</li><li>➤ EN ISO 10993-1:2003 - Medical devices. Biological evaluation of medical devices. Part 1. Evaluation and testing (ITD)</li><li>➤ EN ISO 10993-5:1999 - Medical devices. Biological evaluation of medical devices. Part 5. Tests for in vitro cytotoxicity (ITD)</li><li>➤ EN ISO 10993-10:2002 - Medical devices. Biological evaluation of medical devices. Part 10. Tests for irritation and delayed-type hypersensitivity (ITD)</li></ul> |
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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:

