

June 18, 2018

DECLARATION OF CONFORMITY

Manufacturer: ErgoProduction LLC
Address: Liter N, building 14, corp. 39,
Shkiperskiy protok, 199106 St. Petersburg
Russia

IVD Medical Devices: BioVitrum Tissue marking dyes (see annex No. 1)

WE, the manufacturer, declare and ensure with sole responsibility that products listed above meet the applicable requirements of the European *In Vitro* Diagnostic Directive 98/79/EC.

Device Classification: *Article 9, section 1, "Other" IVD*

Conformity Assessment Route: This declaration is based on conformity assessment procedure of Directive 98/79/EC Annex III.

EC Authorized Representative: Medical Device Safety Service GmbH (MDSS)
Schiffgraben 41
30175 Hannover
Germany

Applied Standards: *EN ISO 13485*
EN ISO 14971
EN ISO 18113-1
EN ISO 18113-2

Signature of Company Representative:

Name: R. Anosov
Title: LLC Ergoproducton Managing Director



Date: June 18, 2018



Annex No. 1.**(page 1/2)**

<i>Product Number</i>	<i>Product Name</i>
19-001/B-6.	BioVitrum Tissue marking dye, black 6 ml
19-001/BL-6.	BioVitrum Tissue marking dye, blue 6 ml
19-001/G-6.	BioVitrum Tissue marking dye, green 6 ml
19-001/Y-6.	BioVitrum Tissue marking dye, yellow 6 ml
19-001/R-6.	BioVitrum Tissue marking dye, red 6 ml
19-001/O-6.	BioVitrum Tissue marking dye, orange 6 ml
19-001/P-6.	BioVitrum Tissue marking dye, purple 6 ml
19-001/6.	BioVitrum Tissue marking dyes 7 x 6 ml
19-001/B-30.	BioVitrum Tissue marking dye, black 30 ml
19-001/BL-30.	BioVitrum Tissue marking dye, blue 30 ml
19-001/G-30.	BioVitrum Tissue marking dye, green 30 ml
19-001/Y-30.	BioVitrum Tissue marking dye, yellow 30 ml
19-001/R-30.	BioVitrum Tissue marking dye, red 30 ml
19-001/O-30.	BioVitrum Tissue marking dye, orange 30 ml
19-001/P-30.	BioVitrum Tissue marking dye, purple 30 ml
19-001/30.	BioVitrum Tissue marking dyes 7 x 30 ml
19-001/B-60.	BioVitrum Tissue marking dye, black 60 ml
19-001/BL-60.	BioVitrum Tissue marking dye, blue 60 ml
19-001/G-60.	BioVitrum Tissue marking dye, green 60 ml
19-001/Y-60.	BioVitrum Tissue marking dye, yellow 60 ml
19-001/R-60.	BioVitrum Tissue marking dye, red 60 ml
19-001/O-60.	BioVitrum Tissue marking dye, orange 60 ml
19-001/P-60.	BioVitrum Tissue marking dye, purple 60 ml
19-001/60.	BioVitrum Tissue marking dyes 7 x 60 ml
19-001/B-250.	BioVitrum Tissue marking dye, black 250 ml
19-001/BL-250.	BioVitrum Tissue marking dye, blue 250 ml
19-001/G-250.	BioVitrum Tissue marking dye, green 250 ml
19-001/Y-250.	BioVitrum Tissue marking dye, yellow 250 ml
19-001/R-250.	BioVitrum Tissue marking dye, red 250 ml
19-001/O-250.	BioVitrum Tissue marking dye, orange 250 ml
19-001/P-250.	BioVitrum Tissue marking dye, purple 250 ml

**Annex No. 1.****(page 2/2)**

Product Number	Product Name
19-001/250.	BioVitrum Tissue marking dyes 7 x 250 ml
19-001/B-500.	BioVitrum Tissue marking dye, black 500 ml
19-001/BL-500.	BioVitrum Tissue marking dye, blue 500 ml
19-001/G-500.	BioVitrum Tissue marking dye, green 500 ml
19-001/Y-500.	BioVitrum Tissue marking dye, yellow 500 ml
19-001/R-500.	BioVitrum Tissue marking dye, red 500 ml
19-001/O-500.	BioVitrum Tissue marking dye, orange 500 ml
19-001/P-500.	BioVitrum Tissue marking dye, purple 500 ml
19-001/500.	BioVitrum Tissue marking dyes 7 x 500 ml
19-001/B-1000.	BioVitrum Tissue marking dye, black 1 l
19-001/BL-1000.	BioVitrum Tissue marking dye, blue 1 l
19-001/G-1000.	BioVitrum Tissue marking dye, green 1 l
19-001/Y-1000.	BioVitrum Tissue marking dye, yellow 1 l
19-001/R-1000.	BioVitrum Tissue marking dye, red 1 l
19-001/O-1000.	BioVitrum Tissue marking dye, orange 1 l
19-001/P-1000.	BioVitrum Tissue marking dye, purple 1 l
19-001/1000.	BioVitrum Tissue marking dyes 7 x 1 l

