

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 Routine Stains (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)*Product Nui Product Name*

05-001/S.	Carazzi's hematoxylin, 250 ml
05-001/M.	Carazzi's hematoxylin, 500 ml
05-001.	Carazzi's hematoxylin, 1 l
20-042/S.	Delafield's hematoxylin, 150 ml
20-042.	Delafield's hematoxylin, 500 ml
20-042/L.	Delafield's hematoxylin, 1 l
05-006/S.	Ehrlich's hematoxylin, 250 ml
05-006/M.	Ehrlich's hematoxylin, 500 ml
05-006.	Ehrlich's hematoxylin, 1 l
05-003/S.	Gill's hematoxylin I, 250 ml
05-003/M.	Gill's hematoxylin I, 500 ml
05-003.	Gill's hematoxylin I, 1 l
05-040/S.	Gill's hematoxylin II, 250 ml
05-040/M.	Gill's hematoxylin II, 500 ml
05-040.	Gill's hematoxylin II, 1 l
05-041/S.	Gill's hematoxylin III, 250 ml
05-041/M.	Gill's hematoxylin III, 500 ml
05-041.	Gill's hematoxylin III, 1 l
05-004/S.	Harris hematoxylin, 250 ml
05-004/M.	Harris hematoxylin, 500 ml
05-004.	Harris hematoxylin, 1 l
05-002/S.	Mayer's hematoxylin, 250 ml
05-002/M.	Mayer's hematoxylin, 500 ml
05-002.	Mayer's hematoxylin, 1 l
21-044.	Heidenhain's iron hematoxylin, 75 ml + 150 ml
21-044/M.	Heidenhain's iron hematoxylin, 500 ml + 1 l
05-071/XS.	Papanicolaou Harris hematoxylin, 250 ml
05-071/S.	Papanicolaou Harris hematoxylin, 500 ml
05-071.	Papanicolaou Harris hematoxylin, 1 l
05-024/S.	Regaud's hematoxylin, 250 ml
05-024/M.	Regaud's hematoxylin, 500 ml

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

05-024.	Regaud's hematoxylin, 1 l
05-007/S.	Weigert's iron hematoxylin - solution A, 250 ml
05-007/M.	Weigert's iron hematoxylin - solution A, 500 ml
05-007.	Weigert's iron hematoxylin - solution A, 1 l
05-008/S.	Weigert's iron hematoxylin - solution B, 250 ml
05-008/M.	Weigert's iron hematoxylin - solution B, 500 ml
05-008.	Weigert's iron hematoxylin - solution B, 1 l
05-042/S.	Eosin Y 0,5% alcoholic, 250 ml
05-042/M.	Eosin Y 0,5% alcoholic, 500 ml
05-042/L.	Eosin Y 0,5% alcoholic, 1 l
05-023/S.	Eosin Y 1% alcoholic, 250 ml
05-023/M.	Eosin Y 1% alcoholic, 500 ml
05-023/L.	Eosin Y 1% alcoholic, 1 l
05-010/S.	Eosin Y 1% aqueous, 250 ml
05-010.	Eosin Y 1% aqueous, 500 ml
05-010/LN.	Eosin Y 1% aqueous, 1 l
05-011/S.	Eosin Y concentrated, 250 ml
05-011.	Eosin Y concentrated, 500 ml
05-011/L.	Eosin Y concentrated, 1 l
05-043/S.	Eosin-phloxine, 250 ml
05-043/M.	Eosin-phloxine, 500 ml
05-043.	Eosin-phloxine, 1 l