

EU Declaration of Conformity

Regulation (EU) 2017/746 of the European Parliament and of the Council (IVDR)

Certificate No. EU0032023-BIOG

Manufacturer: **BioGnost Ltd.**
Medjugorska 59
10040 Zagreb, Croatia

Single Registration Number (SRN): **HR-MF-000022153**

EMDN code: **W01030799** – Histology/cytology reagents - other

BioGnost Ltd. hereby declares with sole responsibility, that products covered by the present declaration are in conformity with the Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices. EU declaration of conformity is issued under the sole responsibility of the manufacturer. Listed products are classified as **Class A** – *In vitro* diagnostics and are in accordance with Annex VIII of the Regulation (EU) 2017/746.

Standards and Directives used in support of conformance to Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices:

EN ISO 9001:2015	Quality management systems - Requirements
EN ISO 13485:2016/A11:2021	Medical devices – Quality management systems - Requirements for regulatory purposes
EN ISO 14001:2015	Environmental management systems - Requirements with guidance for use
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
EN 13612:2002/AC:2002	Performance evaluation of <i>in vitro</i> diagnostic medical devices
EN ISO 18113-1:2011	<i>In vitro</i> diagnostic medical devices - Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	<i>In vitro</i> diagnostic medical devices - Information supplied by the manufacturer (labelling) – Part 2: <i>In vitro</i> diagnostic reagents for professional use
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN ISO 23640:2015	<i>In vitro</i> diagnostic medical devices - Evaluation of stability of <i>in vitro</i> diagnostic reagents

Place, date of issue: Zagreb, 06 February 2023

Responsible person for regulatory compliance
Sanja Mihaljevic
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BioGnost Ltd.

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APPENDIX:
LIST OF PRODUCTS

Group of products: Processing and auxiliary reagents for histology/cytology (Basic UDI-DI: 385889212HPC30799PROCYU)

Product name	Catalogue number	Intended use	UDI-DI
DeHematin, 1000 mL	KO-OT-1L	Depigmentation of tissues fixed in non-buffered formalin	0385888820305
DeHematin, 5000 mL	KO-OT-5L	Depigmentation of tissues fixed in non-buffered formalin	03858890007794
OsteoFast 1, 1000 mL	OF1-OT-1L	Decalcifying solutions	0385888821173
OsteoFast 1, 2500 mL	OF1-OT-2.5L	Decalcifying solutions	03858890005684
OsteoFast 2, 1000 mL	OF2-OT-1L	Decalcifying solutions	0385888821401
OsteoFast 2, 2500 mL	OF2-OT-2.5L	Decalcifying solutions	03858890007855
OsteoSens, 1000 mL	OS-OT-1L	Decalcifying solutions	0385888821470
OsteoSens, 2500 mL	OS-OT-2.5L	Decalcifying solutions	03858890007206
Histanol 50, 1000 mL	H50-1L	Dehydrating and rehydrating agents	0385888829285
Histanol 50, 5000 mL	H50-5L	Dehydrating and rehydrating agents	0385888828783
Histanol 50, 10000 mL	H50-10L	Dehydrating and rehydrating agents	03858892121719
Histanol 70, 1000 mL	H70-1L	Dehydrating and rehydrating agents	0385888821593
Histanol 70, 5000 mL	H70-5L	Dehydrating and rehydrating agents	0385888821609
Histanol 70, 10000 mL	H70-10L	Dehydrating and rehydrating agents	0385888821616
Histanol 80, 1000 mL	H80-1L	Dehydrating and rehydrating agents	0385888821623
Histanol 80, 5000 mL	H80-5L	Dehydrating and rehydrating agents	0385888821647
Histanol 80, 10000 mL	H80-10L	Dehydrating and rehydrating agents	0385888821654
Histanol 95, 1000 mL	H95-1L	Dehydrating and rehydrating agents	0385888821661
Histanol 95, 5000 mL	H95-5L	Dehydrating and rehydrating agents	0385888821685
Histanol 95, 10000 mL	H95-10L	Dehydrating and rehydrating agents	0385888821692
Histanol 96, 1000 mL	H96-1L	Dehydrating and rehydrating agents	0385888827243
Histanol 96, 5000 mL	H96-5L	Dehydrating and rehydrating agents	0385888827366
Histanol 96, 10000 mL	H96-10L	Dehydrating and rehydrating agents	0385888827250
Histanol 96, 20 L	H96-20L	Dehydrating and rehydrating agents	03858892121337
Histanol 100, 1000 mL	H100-1L	Dehydrating and rehydrating agents	0385888821708
Histanol 100, 5000 mL	H100-5L	Dehydrating and rehydrating agents	0385888827618
Histanol 100, 10000 mL	H100-10L	Dehydrating and rehydrating agents	0385888824693
Histanol G, 1000 mL	HG-1L	Dehydrating and rehydrating agents	0385888822231
Histanol G, 5000 mL	HG-5L	Dehydrating and rehydrating agents	03858890008104
Histanol G, 10000 mL	HG-10L	Dehydrating and rehydrating agents	03858890008111
Histanol EP 95, 1000 mL	HEP95-1L	Dehydrating and rehydrating agents	03858890008159
Histanol EP 95, 5000 mL	HEP95-5L	Dehydrating and rehydrating agents	03858890008166
Histanol EP 95, 10000 mL	HEP95-10L	Dehydrating and rehydrating agents	03858890008173
Histanol EP 100, 1000 mL	HEP100-1L	Dehydrating and rehydrating agents	03858890000382
Histanol EP 100, 5000 mL	HEP100-5L	Dehydrating and rehydrating agents	03858890008135
Histanol EP 100, 10000 mL	HEP100-10L	Dehydrating and rehydrating agents	03858890008142
Histanol EP 9010, 1000 mL	HEP91-1L	Dehydrating and rehydrating agents	03858892124697
Histanol EP 9010, 5000 mL	HEP91-5L	Dehydrating and rehydrating agents	03858892124673
Histanol EP 9010, 10000 mL	HEP91-10L	Dehydrating and rehydrating agents	03858892124703
Histanol IP, 1000 mL	HIP-1L	Dehydrating and rehydrating agents	0385888822170
Histanol IP, 5000 mL	HIP-5L	Dehydrating and rehydrating agents	03858890008128
Histanol IP, 10000 mL	HIP-10L	Dehydrating and rehydrating agents	03858890004809
Histanol IP, 20 L	HIP-20L	Dehydrating and rehydrating agents	03858892123621
Histanol M, 1000 mL	HM-1L	Dehydrating and rehydrating agents	0385888822224
Histanol M, 5000 mL	HM-5L	Dehydrating and rehydrating agents	0385888827274
Histanol M, 10000 mL	HM-10L	Dehydrating and rehydrating agents	03858890008098
BioClear, 1000 mL	BC-1L	Clearing and deparaffinization agents	0385888821418
BioClear, 2500 mL	BC-2.5L	Clearing and deparaffinization agents	03858892121290
BioClear, 5000 mL	BC-5L	Clearing and deparaffinization agents	03858890005769
BioClear, 10000 mL	BC-10L	Clearing and deparaffinization agents	03858890007862

BioClear New, 1000 mL	BCN-1L	Clearing and deparaffinization agents	03859891237920
BioClear New, 2500 mL	BCN-2.5L	Clearing and deparaffinization agents	03858890007879
BioClear New, 5000 mL	BCN-5L	Clearing and deparaffinization agents	03858890005813
BioClear New, 10000 mL	BCN-10L	Clearing and deparaffinization agents	03858890006681
Immersion oil, 10x10 mL	IU-1010	Immersion media	03858890007909
Immersion oil, 30 mL	IU-30	Immersion media	03858890006292
Immersion oil, 100 mL	IU-100	Immersion media	03858888821197
Immersion oil, 250 mL	IU-250	Immersion media	03858888821203
Immersion oil, 500 mL	IU-500	Immersion media	03858888821210
Immersion oil, 5000 mL	IU-5L	Immersion media	03858892121788
Immersion oil type A, 10x10 mL	IUA-1010	Immersion media	03858890007916
Immersion oil type A, 30 mL	IUA-30	Immersion media	03858890005479
Immersion oil type A, 100 mL	IUA-100	Immersion media	03858888829810
Immersion oil type A, 250 mL	IUA-250	Immersion media	03858890001549
Immersion oil type A, 500 mL	IUA-500	Immersion media	03858888829827
Immersion oil type A, 5000 mL	IUA-5L	Immersion media	03858892124079
Immersion oil type FF, 100 mL	IUF-100	Immersion media	03858890001501
Immersion oil type FF, 250 mL	IUF-250	Immersion media	03858890007985
Immersion oil type FF, 500 mL	IUF-500	Immersion media	03858890007992
Immersion oil type 37, 100 mL	IU37-100	Immersion media	03858890001518
Immersion oil type 37, 250 mL	IU37-250	Immersion media	03858890007961
Immersion oil type 37, 500 mL	IU37-500	Immersion media	03858890007978
Immersion oil, tropical grade, 10x10 mL	IUT-1010	Immersion media	03858892122792
Immersion oil, tropical grade, 30 mL	IUT-30	Immersion media	03858890008920
Immersion oil, tropical grade, 100 mL	IUT-100	Immersion media	03858890003703
Immersion oil, tropical grade, 250 mL	IUT-250	Immersion media	03858890007947
Immersion oil, tropical grade, 500 mL	IUT-500	Immersion media	03858890007954
Immersion oil type C, 100 mL	IUC-100	Immersion media	03858890003710
Immersion oil type C, 250 mL	IUC-250	Immersion media	03858890007923
Immersion oil type C, 500 mL	IUC-500	Immersion media	03858890007930
Clean Lens, solution 1, 100 mL	CL1-OT-100	Cleaning solutions for microscope lens and slides	03858892120873
Clean Lens, solution 2, 100 mL	CL2-OT-100	Cleaning solutions for microscope lens and slides	03858890006919
Clean Lens, solution 3, 100 mL	CL3-OT-100	Cleaning solutions for microscope lens and slides	03858892121009
Acid alcohol, 500 mL	KA-OT-500	Differentiation and bluing reagents	03858892124864
Acid alcohol, 1000 mL	KA-OT-1L	Differentiation and bluing reagents	03858888820282
Acid alcohol, 2500 mL	KA-OT-2.5L	Differentiation and bluing reagents	03858890007480
HCL Pap reagent, 1000 mL	HCLPAP-OT-1L	Differentiation and bluing reagents	03858890000894
HCL Pap reagent, 2500 mL	HCLPAP-OT-2.5L	Differentiation and bluing reagents	03858890008012
Scott's solution, 1000 mL	SC-OT-1L	Differentiation and bluing reagents	03858888820268
Scott's solution, 2500 mL	SC-OT-2.5L	Differentiation and bluing reagents	03858890007640
Bluing reagent, 500 mL	BR-OT-500	Differentiation and bluing reagents	03858892124857
Bluing reagent, 1000 mL	BR-OT-1L	Differentiation and bluing reagents	03858888823504
Bluing reagent, 2500 mL	BR-OT-2.5L	Differentiation and bluing reagents	03858888823511
Ethyl alcohol 50, denatured, 1000 mL	ET50-1L	Dehydrating and rehydrating agents	03858892121627
Ethyl alcohol 50, denatured, 5000 mL	ET50-5L	Dehydrating and rehydrating agents	03858892124741
Ethyl alcohol 50, denatured, 10000 mL	ET50-10L	Dehydrating and rehydrating agents	03858892124758
Ethyl alcohol 50, denatured, 20000 mL	ET50-20L	Dehydrating and rehydrating agents	03858892124765
Ethyl alcohol 70, denatured, 1000 mL	ET70-1L	Dehydrating and rehydrating agents	03858890000788
Ethyl alcohol 70, denatured, 5000 mL	ET70-5L	Dehydrating and rehydrating agents	03858892120699
Ethyl alcohol 70, denatured, 10000 mL	ET70-10L	Dehydrating and rehydrating agents	03858890000801
Ethyl alcohol 70, denatured, 20000 mL	ET70-20L	Dehydrating and rehydrating agents	03858892124734
Ethyl alcohol 80, denatured, 1000 mL	ET80-1L	Dehydrating and rehydrating agents	03858892124772
Ethyl alcohol 80, denatured, 5000 mL	ET80-5L	Dehydrating and rehydrating agents	03858892124789
Ethyl alcohol 80, denatured, 10000 mL	ET80-10L	Dehydrating and rehydrating agents	03858892124796
Ethyl alcohol 80, denatured, 20000 mL	ET80-20L	Dehydrating and rehydrating agents	03858892124802
Ethyl alcohol 95, denatured, 1000 mL	ET95-1L	Dehydrating and rehydrating agents	03858892124819

Ethyl alcohol 95, denatured, 5000 mL	ET95-5L	Dehydrating and rehydrating agents	03858892124826
Ethyl alcohol 95, denatured, 10000 mL	ET95-10L	Dehydrating and rehydrating agents	03858892124833
Ethyl alcohol 95, denatured, 20000 mL	ET95-20L	Dehydrating and rehydrating agents	03858892124840
Ethyl alcohol 96, denatured, 1000 mL	ET96-1L	Dehydrating and rehydrating agents	03858890000795
Ethyl alcohol 96, denatured, 5000 mL	ET96-5L	Dehydrating and rehydrating agents	03858892120835
Ethyl alcohol 96, denatured, 10000 mL	ET96-10L	Dehydrating and rehydrating agents	03858890000818
Ethyl alcohol 96, denatured, 20000 mL	ET96-20L	Dehydrating and rehydrating agents	03858892120804
Ethyl alcohol 100, denatured, 1000 mL	ET100-1L	Dehydrating and rehydrating agents	03858890006094
Ethyl alcohol 100, denatured, 5000 mL	ET100-5L	Dehydrating and rehydrating agents	03858890009002
Ethyl alcohol 100, denatured, 10000 mL	ET100-10L	Dehydrating and rehydrating agents	03858892120934
Ethyl alcohol 100, denatured, 20000 mL	ET100-20L	Dehydrating and rehydrating agents	03858892124727