

EU Declaration of Conformity

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

Certificate No. EU0012023-BIOG

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

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

EMDN code: **W01030705** – Fixing reagents (histology/cytology)

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, 26 July 2023

Responsible person for regulatory compliance:

Sanja Mihaljevic
Executive director
BioGnost Ltd.

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APPENDIX:

LIST OF PRODUCTS

Group of products: Fixatives (Basic UDI-DI: 385889212HPC30705FIXAQX)

Product name	Catalogue number	Intended use	UDI-DI
4% NB Formaldehyde, 1 L	FNB4-1L	Fixation of histological and/or cytological samples	03858888820114
4% NB Formaldehyde, 5 L	FNB4-5L	Fixation of histological and/or cytological samples	03858888820138
4% NB Formaldehyde, 10 L	FNB4-10L	Fixation of histological and/or cytological samples	03858888820145
4% NB Formaldehyde, 20 L	FNB4-20L	Fixation of histological and/or cytological samples	03858888820152
4% Formaldehyde, 1 L	F4-1L	Fixation of histological and/or cytological samples	03858888828943
4% Formaldehyde, 5 L	F4-5L	Fixation of histological and/or cytological samples	03858892124178
4% Formaldehyde, 10 L	F4-10L	Fixation of histological and/or cytological samples	03858890007725
4% Formaldehyde, 20 L	F4-20L	Fixation of histological and/or cytological samples	03858890007732
10% NB Formaldehyde, 1 L	FNB10-1L	Fixation of histological and/or cytological samples	03858888820169
10% NB Formaldehyde, 5 L	FNB10-5L	Fixation of histological and/or cytological samples	03858888820183
10% NB Formaldehyde, 10 L	FNB10-10L	Fixation of histological and/or cytological samples	03858888820190
10% NB Formaldehyde, 20 L	FNB10-20L	Fixation of histological and/or cytological samples	03858888820206
ImmunoForm, 1 L	IMF-1L	Fixation of histological and/or cytological samples	03858892121146
ImmunoForm, 5 L	IMF-5L	Fixation of histological and/or cytological samples	03858892121672
ImmunoForm, 10 L	IMF-10L	Fixation of histological and/or cytological samples	03858892121689
10% Formaldehyde, 1 L	F10-1L	Fixation of histological and/or cytological samples	03858888828738
10% Formaldehyde, 5 L	F10-5L	Fixation of histological and/or cytological samples	03858890007763
10% Formaldehyde, 10 L	F10-10L	Fixation of histological and/or cytological samples	03858890007756
10% Formaldehyde, 20 L	F10-20L	Fixation of histological and/or cytological samples	03858890007749
Formaldehyde 37% for use in histology, 1 L	F37H-1L	Fixation of histological and/or cytological samples	03858890002409
Formaldehyde 37% for use in histology, 2.5 L	F37H-2.5L	Fixation of histological and/or cytological samples	03858892123027
Formaldehyde 37% for use in histology, 5 L	F37H-5L	Fixation of histological and/or cytological samples	03858890001198
Formaldehyde 37% for use in histology, 10 L	F37H-10L	Fixation of histological and/or cytological samples	03858890002645
Formaldehyde 37% for use in histology, 20 L	F37H-20L	Fixation of histological and/or cytological samples	03858890005677
NB Formaldehyde concentrated 5x, 1 L	FK5X-1L	Fixation of histological and/or cytological samples	03858890007824
NB Formaldehyde concentrated 5x, 5 L	FK5X-5L	Fixation of histological and/or cytological samples	03858890007817
NB Formaldehyde concentrated 5x, 10 L	FK5X-10L	Fixation of histological and/or cytological samples	03858890007800

BioFix, 500 mL	BF-500	Fixation of histological and/or cytological samples	03858888829803
BioFix, 1 L	BF-1L	Fixation of histological and/or cytological samples	03858890007770
BioFix C, 500 mL	BFC-500	Fixation of histological and/or cytological samples	03858890007688
BioFix C, 1 L	BFC-1L	Fixation of histological and/or cytological samples	03858890005745
BioFix C, 5 L	BFC-5L	Fixation of histological and/or cytological samples	03858890006957
BioFix GL, 500 mL	BFGL-500	Fixation of histological and/or cytological samples	03858892122488
BioFix GL, 1 L	BFGL-1L	Fixation of histological and/or cytological samples	03858892122495
BioFix GL, 5 L	BFGL-5L	Fixation of histological and/or cytological samples	03858892122501
BioFix HD, 500 mL	BFHD-500	Fixation of histological and/or cytological samples	03858890003536
BioFix HD, 1 L	BFHD-1L	Fixation of histological and/or cytological samples	03858890003543
BioFix HD, 5 L	BFHD-5L	Fixation of histological and/or cytological samples	03858892121702
BioForm S, 1 L	BIOS-OT-1L	Fixation of histological and/or cytological samples	03858888821517
BioForm S, 5 L	BIOS-OT-5L	Fixation of histological and/or cytological samples	03858892121696
Bouin's solution, 100 mL	BOU-OT-100	Fixation of histological and/or cytological samples	03858890000665
Bouin's solution, 1 L	BOU-OT-1L	Fixation of histological and/or cytological samples	03858888821487
Bouin's solution, 5 L	BOU-OT-5L	Fixation of histological and/or cytological samples	03858890007787
Bouin's solution, 10 L	BOU-OT-10L	Fixation of histological and/or cytological samples	03858888821500
CitoFix, 1 L	CX-1L	Fixation of histological and/or cytological samples	03858888823139
CitoSpray, 100 mL	CS-100	Fixation of histological and/or cytological samples	03858888821548
CitoSpray solution, 1 L	CS-1L	Fixation of histological and/or cytological samples	03858888821555
CitoSpray solution, 20 L	CS-20L	Fixation of histological and/or cytological samples	03858892120996
Saccomano's fixative, 500 mL	SF-OT-500	Fixation of histological and/or cytological samples	03858892121771
Saccomano's fixative, 1 L	SF-OT-1L	Fixation of histological and/or cytological samples	03858892120200
Saccomano's fixative, 2.5 L	SF-OT-2.5L	Fixation of histological and/or cytological samples	03858892124871
Saccomano's fixative, 5 L	SF-OT-5L	Fixation of histological and/or cytological samples	03858892121726