

EU Declaration of Conformity

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

Certificate No. EU0022023-BIOG

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

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

EMDN code: **W01030706 – Mounting media (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 in vitro diagnostic medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) – Part 2: In vitro 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	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents

Place, date of issue: Zagreb, 06 February 2023

Responsible person for regulatory compliance:
Sanja Mihaljevic
Executive director
BioGnost Ltd.

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APPENDIX:

LIST OF PRODUCTS

Group of products: Mounting media (Basic UDI-DI: 385889212HPC30706MOUNUA)

Product name	Catalogue number	Intended use	UDI-DI
BioMount DPX, 100 mL	BM-100	Covering/mounting media	03858888821456
BioMount DPX, 250 mL	BM-250	Covering/mounting media	03858888821463
BioMount DPX, 500 mL	BM-500	Covering/mounting media	03858888821449
BioMount DPX High, 100 mL	BMH-100	Covering/mounting media	03858888821319
BioMount DPX High, 250 mL	BMH-250	Covering/mounting media	03858888821326
BioMount DPX High, 500 mL	BMH-500	Covering/mounting media	03858888821333
BioMount DPX Low, 100 mL	BML-100	Covering/mounting media	03858888821272
BioMount DPX Low, 250 mL	BML-250	Covering/mounting media	03858888821289
BioMount DPX Low, 500 mL	BML-500	Covering/mounting media	03858888821296
BioMount DPX New, 100 mL	BMLE-100	Covering/mounting media	03858890002553
BioMount DPX New, 250 mL	BMLE-250	Covering/mounting media	03858890008883
BioMount DPX New, 500 mL	BMLE-500	Covering/mounting media	03858890008890
BioMount New, 30 mL	BMN-30	Covering/mounting media	03858892121139
BioMount New, 100 mL	BMN-100	Covering/mounting media	03858888821371
BioMount New, 250 mL	BMN-250	Covering/mounting media	03858888822163
BioMount New, 500 mL	BMN-500	Covering/mounting media	03858888822309
BioMount New Low, 30 mL	BMNL-30	Covering/mounting media	03858890006391
BioMount New Low, 100 mL	BMNL-100	Covering/mounting media	03858890002560
BioMount New Low, 250 mL	BMNL-250	Covering/mounting media	03858890007886
BioMount New Low, 500 mL	BMNL-500	Covering/mounting media	03858890006056
BioMount, 100 mL	BMT-100	Covering/mounting media	03858888829216
BioMount, 250 mL	BMT-250	Covering/mounting media	03858888829223
BioMount, 500 mL	BMT-500	Covering/mounting media	03858888829230
BioMount, 5000 mL	BMT-5L	Covering/mounting media	03858892121429
BioMount High, 100 mL	BMTH-100	Covering/mounting media	03858888829780
BioMount High, 250 mL	BMTH-250	Covering/mounting media	03858890004540
BioMount High, 500 mL	BMTH-500	Covering/mounting media	03858890001273
BioMount M, 100 mL	BMM-100	Covering/mounting media	03858888821234
BioMount M, 250 mL	BMM-250	Covering/mounting media	03858888821241
BioMount M, 500 mL	BMM-500	Covering/mounting media	03858888821258
BioMount C, 100 mL	BMC-100	Covering/mounting media	03858888829247
BioMount C, 250 mL	BMC-250	Covering/mounting media	03858888829254
BioMount C, 500 mL	BMC-500	Covering/mounting media	03858888829261
BioMount Aqua, 30 mL	BMA-30	Covering/mounting media	03858890009637
BioMount Aqua, 100 mL	BMA-100	Covering/mounting media	03858888823160
BioMount Aqua, 250 mL	BMA-250	Covering/mounting media	03858890007893
BioMount Aqua, 500 mL	BMA-500	Covering/mounting media	03858890007497