Declaration of Conformity

in accordance with ISO/IEC 17050-1

European Community Council Directive 98/79/EC

Manufacturer:	**Immucor, Inc.** 3130 Gateway Drive Norcross, Georgia 30071 USA Phone: +1-770-441-2051 Fax: +1-770-441-3807

Immucor, Inc., hereby declares that the device(s) listed comply with the *In Vitro* Diagnostic Medical Devices Directive 98/79/EC (IVDD) essential requirements and carry the CE marking according. The Self-Declared devices are in accordance with Annex III (EC Declaration of Conformity) of the IVDD.

Standards and Directives used in support of conformance to the *In Vitro* Diagnostic Medical Devices Directive 98/79/EC:

EN ISO 13485:2016+A11:2021	Quality management systems – Medical devices – Requirements for regulatory purposes [ISO 13485:2016]
EN ISO 14971:2012+A11:2021	Medical devices – Application of risk management to medical devices [ISO 14971:2019]
EN13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	*In vitro* diagnostic medical devices – Evaluation of stability of *in vitro* diagnostic reagents [ISO 23640:2011]
EN 13641:2002	Elimination or reduction of risk of infection related to *in vitro* diagnostic reagents
ISO 20417:2021	Medical devices – Information supplied by the manufacturer
EN ISO 15223-1:2021	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements [ISO 15223-1:2021]
EN ISO 18113-1:2011	*In vitro* diagnostic medical devices – Information supplied by the manufacturer (labelling). Part 1: Terms, definitions and general requirements [ISO 18113-1:2009]
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 [ISO 15223-2:2009]
EN ISO 18113-3:2011	*In vitro* diagnostic medical devices – Information supplied by the manufacturer (labelling). Part 3: In vitro diagnostic instruments for professional use [ISO 18113-3:2009]
Regulation (EC) No 1272/2008	On classification, labeling and packaging of substances and mixtures, amending and repealing Directives 76/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
EN 62366-1:2015+A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices [IEC 62366-1:2015/AMD 1:2020]

EC Authorized Representative:	**Immucor Medizinische Diagnostik GmbH** Robert-Bosch-Strasse 32 63303 Dreieich, Germany Phone: +49-6074-8420-0 Fax: +49-6074-8420-99

This declaration is issued under the sole responsibility of Immucor, Inc. by,

Place / Date of issue: Norcross, Georgia USA / 20 September 2022

DocuSigned by Howard Yorek

Howard Yorek | I am the author of this document
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Howard Yorek
Senior Director, Regulatory Affairs

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Reagentai skirti *in vitro*

***In vitro* diagnostic medical devices:**

Art.-Nr. / Art.- no.	Produktbezeichnung / Product designation	Classification:
0066246 (1 plate)	Capture-P®	Self-Declared
0066251 (5 plates)	Capture-P®	Self-Declared
0066247 (1 plate)	Capture-P® Ready-Screen®	Self-Declared
0066240 (1x11.5mL)	Capture-P® Indicator Red Cells	Self-Declared
0066248 (Kit)	Capture-P® Positive Control Serum (Weak) Capture-P® Negative Control	Self-Declared
0006445 (1 plate)	Capture-R Select	Self-Declared
0006446 (5 plates)	Capture-R Select	Self-Declared
0057319 (10x5mL)	W.A.R.M.	Self-Declared
0057316 (8 tests)	RESt®	Self-Declared
0057320 (10x1mL)	H.P.C. (Human Platelet Concentrate)	Self-Declared
0057292 (10x2mL)	Freeze-Dried Papain	Self-Declared
0007930 (1x3mL)	Complement Control Cells	Self-Declared
0066122 (1x10mL)	DAT Positive Control Cell	Self-Declared
0066125 (4x10mL)	DAT Positive Control Cell	Self-Declared
0007893 (Kit)	FMH RapidScreen	Self-Declared
0007537 (1x5mL)	Anti-k	Self-Declared
0007540 (1x2mL)	Anti-Kp^a	Self-Declared
0007550 (1x2mL)	Anti-Kp^b	Self-Declared
0004817 (1x5mL)	Anti-k (Monoclonal)(IgG) Gamma-clone®	Self-Declared
0004819 (1x5mL)	Anti-C^w (Monoclonal) Gamma-clone®	Self-Declared
0004814 (1x5mL)	Anti-S (Monoclonal) Gamma-clone®	Self-Declared
0066428 (1x5mL)	Anti-S (Monoclonal) Gamma-clone®	Self-Declared
0004815 (1x5mL)	Anti-s (Monoclonal) Gamma-clone®	Self-Declared
0066429 (1x5mL)	Anti-s (Monoclonal) Gamma-clone®	Self-Declared
0004861 (1x5mL)	Anti-Le^a (Murine Monoclonal) Gamma-clone®	Self-Declared
0004864 (1x5mL)	Anti-Le^b (Murine Monoclonal) Gamma-clone®	Self-Declared
0007865 (Kit)	Gamma® EGA Kit	Self-Declared
0007861 (Kit)	Gamma® ELU-Kit II	Self-Declared
0007702 (1x2mL)	Gamma® Lewis Blood Group Substance	Self-Declared
0007700 (1x2mL)	Gamma® P_1 Blood Group Substance	Self-Declared
0007890 (1x10mL)	Gamma®-Quin	Self-Declared
0007056 (1x10mL)	GammaZyme-F	Self-Declared
0007058 (1x10mL)	GammaZyme-B	Self-Declared
0066260 (5 plates)	Automated C3d Plate	Self-Declared