IMMUCOR

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
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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 List A and List B devices are in accordance with Annex IV (Full Quality Assurance) 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	Medical devices – Application of risk management to medical devices [ISO 14971:2007, corrected version 2007-10-01]
EN ISO 14971:2019	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 62366-1:2015+A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices [IEC 62366-1:2015/AMD 1:2020]
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.

EC Authorized Representative: **Immucor Medizinische Diagnostik GmbH**
Robert-Bosch-Strasse 32
63303 Dreieich, Germany
Phone: +49-6074-8420-0
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Digitally signed by Talpiş Andrei
Date: 2023.07.12 11:52:43 EEST
Reason: MoldSign Signature
Location: Moldova

Notified body: TÜV Rheinland LGA Products GmbH – 0197

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Conformity assessment for Annex IV and Annex II, List A and List B devices, performed by:

TÜV Rheinland LGA Products GmbH (0197)
Tillystraße 2
90431 Nürnberg
Germany
Phone: +49 (0) 911 655-5227

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

Place / Date of issue: Norcross, Georgia USA / 14 April 2022

Howard Yorek
Senior Director, Regulatory Affairs

State of Georgia
County of: Dekalb

To the best of my knowledge, this document is neither a public record nor a publicly reorderable document, or an available certified document from an official source other than a notary public. I, **Marlene Jones**, a notary public, do hereby certify that on this **14th day of April, 2022**, personally appeared before me **Howard Yorek**, declared that he signed the foregoing document as the Senior Director, Regulatory Affairs and that the statements therein contained are true to the best of his knowledge.

14APR2022
Signature of Marlene Jones, Notary Public

Seal:

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In Vitro diagnostic medical devices:

Art.-Nr. / Art.- no.	Produktbezeichnung / Product designation:	Classification:
0002410 (2x11.5mL)	corQC® Test System	List A
0066296 (1x10mL)	corQC® EXTEND Standard	List A
0002417 (3x5mL)	corQC® EXTEND 1, 2, and 3	List A
0066297 (Kit)	corQC® EXTEND Complete	List A
0002995 (1x5mL)	Weak D Cells	List A
0002338 (4x10mL)	Referencells® A_1, A_2, B and O	List A
0002345 (2x10mL)	Referencells® A_1 and B	List A
0002342 (1x10mL)	Referencells® A_2	List A
0066090 (8x4.5mL)	WB corQC®	List A
0066087 (1x10mL)	Monoclonal Control	List A
0066089 (10x10mL)	Monoclonal Control	List A

Art.-Nr. / Art.- no.	Produktbezeichnung / Product designation:	Classification:
0004812 (1x5mL)	Anti-Jk^a (Monoclonal) Gamma-clone®	List B
0066426 (1x5mL)	Anti-Jk^a (Monoclonal) Gamma-clone®	List B
0004813 (1x5mL)	Anti-Jk^b (Monoclonal) Gamma-clone®	List B
0066427 (1x5mL)	Anti-Jk^b (Monoclonal) Gamma-clone®	List B
0004816 (1x5mL)	Anti-Fy^a (Monoclonal) (IgG) Gamma-clone®	List B
0066430 (1x5mL)	Anti-Fy^a (Monoclonal) (IgG) Gamma-clone®	List B
0004818 (1x5mL)	Anti-Fy^b (Monoclonal) Gamma-clone®	List B
0401510 (10x10mL)	Anti-IgG (Murine Monoclonal) Gamma-clone®	List B
0409203 (3x10mL)	Anti-IgG (Murine Monoclonal) Gamma-clone® (Green)	List B
0409210 (10x10mL)	Anti-IgG (Murine Monoclonal) Gamma-clone® (Green)	List B
0401010 (10x10mL)	Anti-IgG,-C3d; Polyspecific (Murine Monoclonal) Gamma-clone®	List B
0409703 (3x10mL)	Anti-IgG,-C3d; Polyspecific (Murine Monoclonal) Gamma-clone® (Green)	List B
0409710 (10x10mL)	Anti-IgG,-C3d; Polyspecific (Murine Monoclonal) Gamma-clone® (Green)	List B
0005020 (20x3mL)	Panocell®-20	List B
0002332 (16x3mL)	Panocell®-16	List B
0003032 (12x3mL)	Panocell®-10	List B
0002385 (24x3mL)	Panocell®-10, Ficin-Treated	List B
0002223 (1x10mL)	Hemantigen® (Pooled Cells)	List B
0002378 (2x10mL)	Panoscreen® I and II	List B
0002380 (2x10mL)	Panoscreen® I and II	List B
0002390 (2x10mL)	Panoscreen® I and II	List B
0002377 (3x10mL) *Cw*	Panoscreen® I, II and III	List B
0002381 (3x10mL)	Panoscreen® I, II and III	List B
0002383 (4x5mL,1x10mL)	Panoscreen® EXTEND	List B
0066204 (1 plate)	Capture-R® Ready-ID®	List B
0066214 (5 plates)	Capture-R® Ready-ID®	List B
0006454 (1 plate)	Capture-R® Ready-ID® Extend I	List B
0006455 (5 plates)	Capture-R® Ready-ID® Extend I	List B
0006456 (1 plate)	Capture-R® Ready-ID® Extend II	List B
0006457 (5 plates)	Capture-R® Ready-ID® Extend II	List B
0006439 (1 plate)	Capture-R® Ready-Screen® (I and II)	List B

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0006440 (5 plates)	Capture-R® Ready-Screen® (I and II)	List B
0066202 (1 plate) *Cw*	Capture-R® Ready-Screen® (I and II)	List B
0066212 (5 plates) *Cw*	Capture-R® Ready-Screen® (I and II)	List B
0066207 (1 plate) *Dia*	Capture-R® Ready-Screen® (I and II)	List B
0066217 (5 plates) *Dia*	Capture-R® Ready-Screen® (I and II)	List B
0066803 (1 plate)	Capture-R® Ready-Screen® (3)	List B
0066813 (5 plates)	Capture-R® Ready-Screen® (3)	List B
0066804 (1 plate) *Cw Kpa*	Capture-R® Ready-Screen® (3)	List B
0066814 (5 plates) *Cw Kpa*	Capture-R® Ready-Screen® (3)	List B
0066805 (1 plate) *Dia*	Capture-R® Ready-Screen® (3)	List B
0066815 (5 plates) *Dia*	Capture-R® Ready-Screen® (3)	List B
0066816 (5 plates) *Gp.Mur*	Capture-R® Ready-Screen® (3)	List B
0066901 (1 plate) *Gp.Mur*	Capture-R® Ready-Screen® (3)	List B
0006433 (1 plate)	Capture-R® Ready-Screen® (Pooled Cells)	List B
0006436 (5 plates)	Capture-R® Ready-Screen® (Pooled Cells)	List B
0066203 (1 plate) *Cw*	Capture-R® Ready-Screen® (Pooled Cells)	List B
0066213 (5 plates) *Cw*	Capture-R® Ready-Screen® (Pooled Cells)	List B
0066253 (1 plate) *Dia*	Capture-R® Ready-Screen® (Pooled Cells)	List B
0066254 (5 plates) *Dia*	Capture-R® Ready-Screen® (Pooled Cells)	List B
0066802 (1 plate) *Cw Kpa*	Capture-R® Ready-Screen® (4)	List B
0066812 (5 plates) *Cw Kpa*	Capture-R® Ready-Screen® (4)	List B
0006418 (1x57mL)	Capture® LISS	List B
0066231 (6x57mL)	Capture® LISS	List B
0006419 (1x11.5mL)	Capture® LISS	List B
0006420 (10x11.5mL)	Capture® LISS	List B
0006427 (1x11.5mL)	Capture-R® Ready Indicator Red Cells	List B
0006428 (10x11.5mL)	Capture-R® Ready Indicator Red Cells	List B
0066236 (Kit)	Capture-R® Positive Control Serum (Weak) Capture-R® Negative Control Serum	List B
0002322 (1x10mL)	Bovine Albumin Solution 22%	List B
0002327 (10x10mL)	Bovine Albumin Solution 22%	List B
0001205 (1x10mL)	Bovine Albumin Solution 22%	List B
0001206 (1x50mL)	Bovine Albumin Solution 22%	List B
0001209 (10x10mL)	Bovine Albumin Solution 22%	List B
0005070 (6x200mL)	pHix	List B
0705003 (3x10mL)	Gamma® PeG	List B
0705010 (10x10mL)	Gamma® PeG	List B
0705403 (3x10mL)	Gamma® N-HANCE	List B
0705410 (10x10mL)	Gamma® N-HANCE	List B
0002224 (1x10mL)	Checkcell®	List B
0002225 (3x10mL)	Checkcell®	List B
0002226 (1x10mL)	Checkcell® (Weak)	List B
0002227 (3x10mL)	Checkcell® (Weak)	List B
0066206 (1 plate)	Capture-CMV®	List B
0066216 (5 plate)	Capture-CMV®	List B
0066239 (Kit)	Capture-CMV® Positive Control Serum (Weak) Capture-CMV® Negative Control Serum	List B
0066238 (1x11.5mL)	Capture-CMV® Indicator Red Cells	List B