

Declaration of Conformity

European Community Council Directive 98/79/EC

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

Immucor, Inc., hereby declares that the device(s) listed on this form meet the provisions of the council directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer. 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	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]
EN13612:2002/AC:2002	Performance evaluation of <i>in vitro</i> 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
EN ISO 15223-1:2016	Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements [ISO 15223-1:2016, corrected version 2016-12-15]
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]
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.



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

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Notified body: Lloyds Register Quality Assurance (LRQA) 0088

Place, date of issue: Norcross, Georgia, 11 SEP 2018

Howard Yorek
Senior Director, Regulatory Affairs
Immucor, Inc.

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

Lloyd's Register Quality Assurance (0088)

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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 11th day of September, 2018, personally appeared before me **Howard Yorek**, declared that he is the Senior Director, Regulatory Affairs for Immucor, Inc., 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.

Signature of Marlene Jones, Notary Public

Seal:



Product (s):

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 (5mL)	Anti-Jk ^a (Monoclonal) Gamma-clone	List B
0066426 (1x10mL)	Anti-Jk ^a (Monoclonal) Gamma-clone	List B
0004813 (5mL)	Anti-Jk ^b (Monoclonal) Gamma-clone	List B
0066427 (1x10mL)	Anti-Jk ^b (Monoclonal) Gamma-clone	List B
0004816 (5mL)	Anti-Fy ^a (Monoclonal) (IgG) 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 (10mL)	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 (10mL)	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
0066204 (1plate)	Capture-R [®] Ready-ID [®]	List B
0066214 (5plate)	Capture-R [®] Ready-ID [®]	List B
0006454 (1plate)	Capture-R [®] Ready-ID [®] Extend I	List B

0006455	(5plate)	Capture-R [®] Ready-ID [®] Extend I	List B
0006456	(1plate)	Capture-R [®] Ready-ID [®] Extend II	List B
0006457	(5plate)	Capture-R [®] Ready-ID [®] Extend II	List B
0006439	(1plate)	Capture-R [®] Ready-Screen [®] (I and II)	List B
0006440	(5plate)	Capture-R [®] Ready-Screen [®] (I and II)	List B
0066202	(1plate) <i>cw</i>	Capture-R [®] Ready-Screen [®] (I and II)	List B
0066212	(5plate) <i>cw</i>	Capture-R [®] Ready-Screen [®] (I and II)	List B
0066207	(1plate) <i>Dia</i>	Capture-R [®] Ready-Screen [®] (I and II)	List B
0066217	(5plate) <i>Dia</i>	Capture-R [®] Ready-Screen [®] (I and II)	List B
0066803	(1plate)	Capture-R [®] Ready-Screen [®] (3)	List B
0066813	(5plate)	Capture-R [®] Ready-Screen [®] (3)	List B
0066804	(1plate) <i>cw, Kpa</i>	Capture-R [®] Ready-Screen [®] (3)	List B
0066814	(5plate) <i>cw, Kpa</i>	Capture-R [®] Ready-Screen [®] (3)	List B
0066805	(1plate) <i>Dia</i>	Capture-R [®] Ready-Screen [®] (3)	List B
0066815	(5plate) <i>Dia</i>	Capture-R [®] Ready-Screen [®] (3)	List B
0066816	(5plate) <i>Gp. Mur</i>	Capture-R [®] Ready-Screen [®] (3)	List B
0066901	(1plate) <i>Gp. Mur</i>	Capture-R [®] Ready-Screen [®] (3)	List B
0006433	(1plate)	Capture-R [®] Ready-Screen [®] (Pooled Cells)	List B
0006436	(5plate)	Capture-R [®] Ready-Screen [®] (Pooled Cells)	List B
0066203	(1plate) <i>Cw</i>	Capture-R [®] Ready-Screen [®] (Pooled Cells)	List B
0066213	(5plate) <i>Cw</i>	Capture-R [®] Ready-Screen [®] (Pooled Cells)	List B
0066253	(1plate) <i>Dia</i>	Capture-R [®] Ready-Screen [®] (Pooled Cells)	List B
0066254	(5plate) <i>Dia</i>	Capture-R [®] Ready-Screen [®] (Pooled Cells)	List B
0066802	(1plate) <i>cw, Kpa</i>	Capture-R [®] Ready-Screen [®] (4)	List B
0066812	(5plate) <i>cw, Kpa</i>	Capture-R [®] Ready-Screen [®] (4)	List B
0006418	(57mL)	Capture [®] LISS	List B
0066231	(6x57mL)	Capture [®] LISS	List B
0006419	(11.5mL)	Capture [®] LISS	List B
0006420	(10x11.5mL)	Capture [®] LISS	List B
0006427	(11.5mL)	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	(10mL)	Bovine Albumin Solution 22%	List B
0002327	(10x10mL)	Bovine Albumin Solution 22%	List B
0001205	(10mL)	Bovine Albumin Solution 22%	List B
0001206	(50mL)	Bovine Albumin Solution 22%	List B
0001209	(10x10mL)	Bovine Albumin Solution 22%	List B

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Art.-Nr. / Art.- no.	Produktbezeichnung / Product designation	Classification:
0002007 (10mL)	ImmuAdd	List B
0002008 (10x10mL)	ImmuAdd	List B
0002010 (50mL)	ImmuAdd	List B
0002012 (6x50mL)	ImmuAdd	List B
0005070 (6x200mL)	pHix	List B
0705003 (3x10mL)	Gamma PeG	List B
0705010 (10x10mL)	Gamma PeG	List B
0002224 (10mL)	Checkcell	List B
0002225 (3x10mL)	Checkcell	List B
0002226 (10mL)	Checkcell (Weak)	List B
0002227 (3x10mL)	Checkcell (Weak)	List B
0066206 (1plate)	Capture-CMV	List B
0066216 (5plate)	Capture-CMV	List B
0066239 (Kit)	Capture-CMV Positive Control Serum (Weak); Capture-CMV Negative Control Serum	List B
0066238 (11.5mL)	Capture-CMV Indicator Red Cells	List B