

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,

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

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)

1 Trinity Park
Bickenhill Lane
Birmingham B37 7ES
United Kingdom
Phone: +44 24 7688 2309

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 |

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|---------|-------------------------|---|--------|
| 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 |