
European Community Council Directive 98/79/EC

Manufacturer: **Immucor, Inc.**
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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 <i>in vitro</i> diagnostic medical devices |
| EN ISO 23640:2015 | <i>In vitro</i> diagnostic medical devices – Evaluation of stability of <i>in vitro</i> diagnostic reagents [ISO 23640:2011] |
| EN 13641:2002 | Elimination or reduction of risk of infection related to <i>in vitro</i> 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 | <i>In vitro</i> 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 | <i>In vitro</i> diagnostic medical devices – Information supplied by the manufacturer (labelling). Part 2: <i>In vitro</i> 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. |

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Notified body: TÜV Rheinland LGA Products GmbH – 0197



Declaration of Conformity

in accordance with ISO/IEC 17050-1

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

TÜV Rheinland LGA Products GmbH (0197)

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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.

Signature of Marlene Jones, Notary Public

Seal:



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) C _w | 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 |

Declaration of Conformity

in accordance with ISO/IEC 17050-1

| Art.-Nr. / Art.- no. | Produktbezeichnung / Product designation: | Classification: |
|----------------------------------|---|-----------------|
| 0006440 (5 plates) | Capture-R® Ready-Screen® (I and II) | List B |
| 0066202 (1 plate) <i>Cw</i> | Capture-R® Ready-Screen® (I and II) | List B |
| 0066212 (5 plates) <i>Cw</i> | Capture-R® Ready-Screen® (I and II) | List B |
| 0066207 (1 plate) <i>Dia</i> | Capture-R® Ready-Screen® (I and II) | List B |
| 0066217 (5 plates) <i>Dia</i> | 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) <i>Cw Kpa</i> | Capture-R® Ready-Screen® (3) | List B |
| 0066814 (5 plates) <i>Cw Kpa</i> | Capture-R® Ready-Screen® (3) | List B |
| 0066805 (1 plate) <i>Dia</i> | Capture-R® Ready-Screen® (3) | List B |
| 0066815 (5 plates) <i>Dia</i> | Capture-R® Ready-Screen® (3) | List B |
| 0066816 (5 plates) <i>Gp.Mur</i> | Capture-R® Ready-Screen® (3) | List B |
| 0066901 (1 plate) <i>Gp.Mur</i> | 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) <i>Cw</i> | Capture-R® Ready-Screen® (Pooled Cells) | List B |
| 0066213 (5 plates) <i>Cw</i> | Capture-R® Ready-Screen® (Pooled Cells) | List B |
| 0066253 (1 plate) <i>Dia</i> | Capture-R® Ready-Screen® (Pooled Cells) | List B |
| 0066254 (5 plates) <i>Dia</i> | Capture-R® Ready-Screen® (Pooled Cells) | List B |
| 0066802 (1 plate) <i>Cw Kpa</i> | Capture-R® Ready-Screen® (4) | List B |
| 0066812 (5 plates) <i>Cw Kpa</i> | 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 |