EC Certificate

TÜVRheinland®

Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 1804147-1

Digitally signed by Talpiş Andrei
Date: 2022.10.21 14:54:03 EEST
Reason: MoldSign Signature
Location: Moldova

Manufacturer: Immucor, Inc.
3130 Gateway Drive
Norcross GA 30071
USA

Products: Replaces EC Certificate, Registration No.: HL 60139595 0001

Annex II List A Products:

corQC Test System
corQC EXTEND Standard
corQC EXTEND 1, 2 and 3
corQC EXTEND Complete
Monoclonal Control
Weak D cells
Referencells-4 (Group A1, A2, B and O)
Referencells-2 (Group A1 and B)
Referencells-1 (Group A2)
WB corQC

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 3332513-570

Effective date: 2020-12-17

Expiry date: 2024-05-26

Issue date: 2020-12-17

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

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Manufacturer:
Immucor, Inc.
3130 Gateway Drive
Norcross GA 30071
USA

Annex II List B Products:

Checkcell
Checkcell (Weak)
Panoscreen I and II
Panoscreen I, II and III
Panoscreen EXTEND
Panocell-16
Panocell-20
Panocell-10
Panocell-10, Ficin-Treated
Hemantigen
Capture-CMV (Plates)
Capture-CMV Indicator Red Cells
Capture-R Ready-Screen (I and II)
Capture-R Ready-Screen (Pooled Cells)
Capture-R Ready-ID
pHix

Capture-R Ready-ID EXTEND I
Capture-R Ready-ID EXTEND II
Capture-R Ready-Screen (3)
Anti-Jka (Monoclonal) Gamma-clone®
Anti-Jkb (Monoclonal) Gamma-clone®
Gamma PeG
Capture-R Ready-Screen (3)

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Immucor, Inc.
3130 Gateway Drive
Norcross GA 30071
USA

Capture-R Ready-Screen (4)

Anti-Human Globulin, Anti-IgG,-C3d
Polyspecific (Murine Monoclonal) Gamma-Clone®
Anti-Human Globulin, Anti-IgG (Murine Monoclonal)
Gamma-Clone®
Gamma N-HANCE

Capture-CMV Controls (Kit):

Capture-CMV Positive Control Serum (Weak)
Capture-CMV Negative Control Serum

Capture-R Ready Indicator Red Cells
Capture LISS

Capture-R Controls (Kit):

Capture-R Positive Control Serum (Weak)
Capture-R Negative Control Serum

Bovine Albumin Solution 22%
ImmuAdd
Anti-Fya (Monoclonal) Gamma-clone®
Anti-Fyb (Monoclonal) Gamma-clone®

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