Immucor,Inc.

Declaration of Conformity – IVD Reagents

(In accordance with EN /ISO/IEC 170501:2010)
European Community Council Directive 98/79/EC

Immucor, Inc. hereby declares that the device(s) listed in appendix A comply with the UK Statutory Instrument 2002:618, of The Medical Devices Regulations 2002, transposing the In Vitro Diagnostic Medical Devices Directive 98/79/EC (IVDD). The List A and List B devices are in accordance with Annex IV (Full Quality Assurance) of the IVDD. The Self-Declared devices are in accordance with Annex III (EC Declaration of Conformity) of the IVDD.

Standards and Directives used in support of conformance to the In Vitro Diagnostic Medical Devices Directive 98/79/EC:

- EN ISO 13485:2012 - Quality management systems - Medical devices - Requirements for regulatory purposes [ISO 13485:2003]
- EN ISO 14971:2012 - Medical devices - Application of risk management to medical devices [ISO 14971:2007, Corrected Version 2007-10-01]
- EN 13612:2002/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 infection related to in vitro diagnostic reagents
- ISO 14644-1:1999 - Cleanrooms and associated controlled environments - Classification of Air Cleanliness
- ISO 15223-1:2012 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- EN 980:2008 - Symbols for use in the labelling of medical devices
- EN ISO 18113-1:2011 - In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 1: Terms, definitions and general requirements [ISO 15223-1:2009]
- 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

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

Howard Yorek
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Immucor, Inc.

Issue Date: 05 May 2017

Digitally signed by Talpiş Andrei
Date: 2021.02.08 15:09:05 EET
Reason: MoldSign Signature
Location: Moldova

Appendix A: In Vitro Diagnostic Medical Devices
Declaration of Conformity
Immucor, Inc.

List A and List B devices in accordance with Annex IV (Full Quality Assurance) of the IVDD

Classification: Annex II, List A

corQC Test System
corQC EXTEND Standard
corQC EXTEND 1, 2, and 3
corQC EXTEND Complete
Weak D Cells
Referencells-4 (Group A_1, A_2, B,and O)
Referencells-2 (Group A_1 and B)
Referencells-1 (Group A_2)
WB corQC

Classification: Annex II, List B

Bovine Albumin Solution 22%
ImmuAdd
pHix
Checkcell
Checkcell (Weak)
Panoscreen I and II
Panoscreen I, II and III
Hemantigen
Panocell-10
Panocell-16
Panocell-20
Panocell-10, Ficin-Treated
Capture-R Ready-Screen (I and II)
Capture-R Ready Screen (3)
Capture-R Ready-Screen (4)
Capture-R Ready-Screen (Pooled Cells)
Capture-R Ready-ID
Capture-R Ready-ID Extend I
Capture-R Ready-ID Extend II
Capture-CMV
Capture-R Ready Indicator Red Cells
Capture-CMV Indicator Red Cells
Capture LISS
Capture-R Positive Control Serum (Weak)
Capture-R Negative Control Serum
Capture-CMV Positive Control Serum (Weak)
Capture-CMV Negative Control Serum
Anti-Jk^a
Anti-Jk^b
Gamma PeG
Gamma-clone Anti-Human Globulin, Anti-IgG, -C3d; Polyspecific (Murine Monoclonal)
Gamma-clone Anti-Human Globulin, Anti-IgG (Murine Monoclonal)
Gamma-clone Anti- Jk^a (Monoclonal)
Gamma-clone Anti-Jk^b (Monoclonal)
Gamma-clone Anti-Fy^a (Monoclonal)

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

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Appendix A: In Vitro Diagnostic Medical Devices
Declaration of Conformity
Immucor, Inc.

Self-Declared devices in accordance with Annex III (EC Declaration of Conformity) of the IVDD

Classification: Self Certify (Self-Declare), Annex III

Capture-P
Capture-P Ready-Screen
Platelet Wash and Storage Solution
Capture-P Indicator Red Cells
Capture-P Positive Control Serum (Weak)
Capture-P Negative Control Serum
Capture-R Select
Red Blood Cell (RBC) Storage Solution
W.A.R.M.
RESt
H.P.C.
Freeze-Dried Papain
Complement Control Cells
DAT Positive Control Cell
FMH RapidScreen
Fetal Bleed Screening
CMT Plates
Specimen Diluent
Anti-Di^a
Anti-k
Anti-Kp^a
Anti-Kp^b
Gamma-clone Anti-Le^a (Murine Monoclonal)
Gamma-clone Anti-Le^b (Murine Monoclonal)
Gamma-clone Anti-S (Monoclonal)
Gamma-clone Anti-s (Monoclonal)
Anti-S
Anti-s
Gamma EGA Kit
Gamma ELU-Kit II
Gamma Lectin System
Gamma Lewis Blood Group Substance
Gamma P1 Blood Group Substance
Gamma-Quin
GammaZyme-F