



Declaration of Conformity

in accordance with ISO/IEC 17050-1

Regulation (EU) 2017/746 on *In Vitro* Diagnostic Devices (IVDR)

Device: Platelet Wash and Storage Solution
Article №: 0005035
Basic UDI: 88823401W01030399A0000249
Device Classification: Class A (Rule 5)
Intended Purpose:

Reagentai skirti *in vitro*

Platelet Wash and Storage Solution (PWSS) is used to wash, suspend and store (preserve) platelets for use in *in vitro* platelet antibody detection assays. For laboratory professional use to prepare platelets from blood specimens collected from patients and donors for further platelet antibody testing.

Harmonized Standards and Regulations Applied:

EN ISO 13485:2016+A11:2021	Quality management systems – Medical devices – Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN ISO 23640:2015	<i>In vitro</i> diagnostic medical devices – Evaluation of stability of <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
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
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
EN 62366-1:2015+A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
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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Single Registration № (SRN): DE-AR-000007083

Immucor, Inc. hereby declares that this device is in conformity with the requirements of Regulation (EU) 2017/746.



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

DocuSigned by Howard Yorek



Howard Yorek

I approve this document
06-May-2022 | 1:56:22 PM EDT

Howard Yorek
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Senior Director, Regulatory Affairs | Person Responsible for Regulatory Compliance

Place / Date of Issue: Norcross, Georgia USA / 06 May 2022