Declaration of Conformity

in accordance with ISO/IEC 17050-1

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

Device: **Echo Lumena**
Article №: 0086998
Basic UDI: 88823401W0202030102A000QF
Device Classification: Class A (Rule 5)
Intended Purpose:

Immucor's Echo Lumena is a fully automated instrument, which performs standard immunohaematology assays utilizing a microstrip-based platform. Assays include ABO and Rh(D) typing, detection/identification of IgG red blood cell antibodies, compatibility testing, direct antiglobulin test for *in vivo* sensitization of red blood cells and red blood cell phenotyping. Samples which have been loaded onto the instruments are tested for the specific assays specified by the user. The instruments hold all necessary reagents and controls and notify the user if needed reagents are not loaded. The Echo Lumena performs all necessary procedures which include pipetting, incubation, cell washing, centrifugation, and reading results.

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
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	*In vitro* diagnostic medical devices – Information supplied by the manufacturer (labelling). Part 1: Terms, definitions and general requirements
EN ISO 18113-3:2011	*In vitro* diagnostic medical devices – Information supplied by the manufacturer (labelling). Part 2: *In vitro* diagnostic instruments for professional use
EN 62366-1:2015+A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
EN 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 61010-2-010:2003	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61010-2-020:2006	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-020: Particular requirements for laboratory centrifuges
EN 61326-1:2005	Electrical equipment for measurement, control, and laboratory use – EMC requirements – Part 1: General requirements
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use – Part 2-6: Particular requirements – *In vitro* diagnostic (IVD) medical equipment
EN 62304:2006/AC:2008	Medical device software – Software lifecycle processes
EN 62366-1:2015+A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices [IEC 62366-1:2015/AMD 1:2020]
Directive 2011/65/EU	Restriction of the use of certain hazardous substances in electrical and electronic equipment [RoHS 2]
Directive 2015/863/EU	Amending Annex II to Directive 2011/65/EU as regards to the list of restrictive substances [RoHS 3]

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Single Registration № (SRN):	**US-MF-000011568**
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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.

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 | 1:56:00 PM EDT
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Howard Yorek
Senior Director, Regulatory Affairs | Person Responsible for Regulatory Compliance

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