Declaration of Conformity

in accordance with ISO/IEC 17050-1

European Community Council Directive 98/79/EC

Immucor GTI Diagnostics, Inc. hereby declares that the device(s) listed in the Appendix comply with 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 Directive 98/79/EC:

- EN ISO 13485:2016+A11:2021 Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 14971:2019 Medical devices – Application of risk management of medical devices
- BS EN 13612:2002/AC:2002 Performance evaluation of in vitro diagnostic medical devices / Corrigendum: Performance evaluation of in vitro diagnostic medical devices
- ISO 23640:2015 In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
- EN 62366-1:2015 Medical Devices-Application of usability engineering to medical devices
- EN ISO 15223-1:2021 Medical devices - Symbols to be used with medical device labels, labeling 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 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (Professional Use)

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

DocuSigned by Leon Lambry
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30-Jun-2022 | 5:55:46 PM EDT
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Issue Date: 30-Jun-2022

Leon Lambry
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Immucor GTI Diagnostics, Inc.
Waukesha, WI USA

Appendix

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

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

LIFECODES HLA-C eRES SSO Typing Kit (628921)
LIFECODES HLA-DQA1/B1 SSO Typing Kit (628930)
LIFECODES HLA-DPA1/B1 SSO Typing Kit (628936)