Declaration of Conformity

Regulation (EU) 2017/746 of the European parliament and of the council (IVDR)

MANUFACTURER			
Name of Company	**Address**	**Representative**	**SRN**
Immucor GTI Diagnostics, Inc	20925 Crossroads Circle Waukesha, WI 53186 United States	Leon Lambry	US-MF-000020921

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**Telephone/Email**	**SRN**
Immucor Medizinische Diagnostik GmbH	Robert-Bosch-Strasse 32 63303 Dreieich Germany	Phone: +49 (0) 6103 8056-0 Email: germany@immuor.com	DE-AR-000007083

Immucor GTI Diagnostics, Inc. hereby declares that the device(s) listed in Appendix A meet the provisions of regulation (EU) 2017/746 on in-vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer. The devices are classified as Class A devices and are in accordance with Annex IV.

Standards and Directives used in support of conformance to regulation (EU) 2017/746 on in

LIFECODES Taq Polymerase is an accessory reagent solely for use with the following products for use in specific washing and dilution steps, which are specific to the products below:

LIFECODES HLA-AeRES SSO Typing Kits (628913)

LIFECODES HLA-BeRES SSO Typing Kits (628917)

LIFECODES HLA-CeRES SSO Typing Kits (628921)

LIFECODES HLA-DRB1eRES SSO Typing Kits (628925)

LIFECODES HLA-DRB3,4,5 SSO Typing Kits (628927)

LIFECODES HLA-DQA1/B1 SSO Typing Kits (628930)

LIFECODES HLA-DPA1/B1 SSO Typing Kits (628936)

Digitally signed by Talpiș Andrei
Date: 2023.09.24 21:08:39 EEST
Reason: MoldSign Signature
Location: Moldova

vitro diagnostic medical devices:

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 to medical devices.
EN 13612:2002/ AC:2002	Performance evaluation of in vitro diagnostic medical devices / Corrigendum: Performance evaluation of in vitro diagnostic medical devices

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BS EN 23640:2015	In-vitro Diagnostic Medical Devices – Evaluation of stability testing of in vitro diagnostic reagents
EN 13975:2020	Sampling Procedures used for acceptance testing of in vitro diagnostic medical devices
BS EN ISO 18113-1:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
BS EN ISO 18113-2:2011	Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
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
BS EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
BS EN 13641:2020	Elimination or Reduction of Risk of Infection Related to In Vitro Diagnostic Reagents
CLSI EP12-A2, 2nd edition	User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline
CLSI EP07, 3rd edition	Interference Testing in Chemical Chemistry; Approved Guideline
CLSI EP09-A3, 3rd edition	Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline
CLSI EP15-A2 , 2nd edition	User Verification of Performance for Precision and Trueness; Approved Guideline – Second Edition
CLSI EP25-A	Evaluation of Stability of In Vitro Diagnostic Regents; Approved Guideline

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

DocuSigned by Leon Lambry
Leon Lambry | I approve this document
12-May-2022 | 2:29:08 PM EDT
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COMPANY REPRESENTATIVE: Leon Lambry
TITLE: Sr Director, Quality and Regulatory Affairs
PLACE / DATE OF ISSUE: Waukesha, WI USA / 12 May 2022

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Appendix A:

PRODUCT IDENTIFICATION					
Product Name	**Model/ Number**	**GMDN Code and Term**	**Basic UDI-DI**	**Product Description**	**Class and Rule**
LIFECODES Taq Polymerase	628075	60092 DNA amplification enzyme reagent IVD	88823411W01030403C004I	Taq Polymerase is an integral component of the LIFECODES Luminex-based HLA-SSO Typing assays. It is used to amplify the DNA for the LIFECODES HLA-SSO Typing Kits.	Class A Rule 5