Certificate

TÜVRheinland®

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Date: 2024.04.20 11:19:15 EEST
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Quality Management System
EN ISO 13485:2016

Registration No.: SX 1804149-1

Organization: Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha WI 53186
USA

Scope: Design, Development and Manufacture of In Vitro Diagnostic Medical Devices, Reagents and Software Used in the Management of Immune Status, Coagulation, Tissue and Immunological Typing.
Distribution of In Vitro Diagnostic Analyzers and Reagents.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 3333169-70
Effective date: 2022-01-04
Expiry date: 2024-01-03
Issue date: 2021-12-13

TÜV Rheinland LGA Products GmbH
TÜVRheinland

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Amy L Cochran
NOTARY
PUBLIC
STATE OF WISCONSIN

State of Wisconsin County of Waukesha
I certify that this is a true and correct copy of a document in the possession of Sateesh Kyasaram which was copied on March 23, 2023.
1 / 1
Notary Amy L. Cochran Notary's expiration date: March 28, 2025

IMMUCOR

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.

Streptavidin-PE (SAPE) is an additional required Reagent that consists of an R-Phycoerythrin Streptavidin Conjugate that acts as ta fluorescent reporter molecule with the following qualitative manual 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)

Standards and Directives used in support of conformance to regulation (EU) 2017/746 on in 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 | 2:29:00 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 Streptavidin-PE	628511	57783 Streptavidin-enzyme conjugate reagent IVD	88823411W01030403C004K	Streptavidin-PE is a required component of the LIFECODES Luminex-based HLA-SSO Typing assays. This reagent can also be used as general reagent for other laboratory applications to detect biotinylated protein and nucleic acids.	Class A Rule 5

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