Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Digitally signed by Talpiș Andrei
Date: 2023.09.24 21:43:08 EEST
Reason: MoldSign Signature
Location: Moldova

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **„Zeticon" S.R.L.** , cu sediul mun. Chisinau, bd. Moscova 9/5, of. 49,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Reactivi „Lifecodes" Immucor GTI Diagnostics (anexa 3);

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura* _____

Andrei TALPIS – Administrator *Data 25.09.2023*

Anexa nr. 3 Lista dispozitivelor medicale solicitate catre notificare LIFECODES

Nr.	Numarul de catalog	Denumire generica (denumirea dispozitivului)	Denumirea comerciala (brand)	Modelul	Cod GMDN	Lista
		Capture R System				
1	628913	LIFECODESS HLA-A eRES SSO Typing kit	Immucor GTI Diagnostics			
2	628917	LIFECODESS HLA-B eRES SSO Typing kit	Immucor GTI Diagnostics			
3	628921	LIFECODESS HLA-C eRES SSO Typing kit	Immucor GTI Diagnostics			
4	628925	LIFECODESS HLA-DRB1 eRES SSO Typing kit	Immucor GTI Diagnostics			
5	628930	LIFECODESS HLA-DQA1/B1 eRES SSO Typing kit	Immucor GTI Diagnostics			
6	628075	LIFECODES Taq Polymerase	Immucor GTI Diagnostics			
7	628511	LIFECODES Streptavidin/PE	Immucor GTI Diagnostics			
8	628222	LIFECODES Serum Cleaner	Immucor GTI Diagnostics			
9	405467	LIFECODES PC-AHG	Immucor GTI Diagnostics			
10	405510	LIFECODES PHS	Immucor GTI Diagnostics			
11	405463	ABC Bulk Rabbit Complement	Immucor GTI Diagnostics			
	265100	LIFECODES LSA I	Immucor GTI Diagnostics			
	265200	LIFECODES LSA II	Immucor GTI Diagnostics			

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Letter of Authorization

Date: September 21, 2023

To Whom It May Concern,

Subject: Letter of Authorization for authorized representative.

We, lmmucor GTI Diagnostics, Inc., as the Product Owner, hereby authorize ZETICON SRL with official address at 9/5 Moscova Boulevard, Office 49 MD – 2068 Chisinau, Republic of Moldova as the Registrant to prepare and submit applications for evaluating and registering medical devices to the respective government body, on our behalf. lmmucor GTI Diagnostics, Inc. at 20925 Crossroads Circle, Waukesha WI 53186 USA hereby authorizes ZETICON SRL, with official address at 9/5 Moscova Boulevard, Office 49 MD – 2068 Chisinau, Republic of Moldova to take the following actions on behalf of lmmucor:

(1) Distribute lmmucor's products.
(2) Participate in public tenders; direct RFQ
(3) Pursue and manage product registrations and other regulatory approvals.

This authorization shall apply to the following medical devices:

Product	Product Code
LIFECODES HLA-A eRES SSO Typing Kit	628913
LIFECODES HLA-B eRES SSO Typing Kit	628917
LIFECODES HLA-C eRES SSO Typing Kit	628921
LIFECODES HLA-DRB1 eRES Typing Kit	628925
LIFECODES HLA-DQA1/B1 SSO Typingkit	628930
LIFECODES LSA I	265100
LIFECODES LSA II	265200
LIFECODES Taq Polymerase	628075
LIFECODES Streptavidin/PE	628511

Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186 USA
855.466.8267
www.immucor.com

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Below are the General-Purpose Reagents:

Product	Product Code
LIFECODES Serum Cleaner	628222
LIFECODES PC-AHG	405467
LIFECODES PHS	405510
ABC Bulk Rabbit Complement	405463

This authorization shall remain in effect until our notification to the Ministry of Health in writing that the authorization is revoked.

Yours Sincerely,

DocuSigned by Leon Lambry

Leon Lambry | I approve this document
21-Sep-2023 | 9:41:38 AM EDT

E3B58FCCAF164A3682C4262594E6953A

Leon Lambry,

Sr. Director, Quality and Regulatory Affairs

Immucor GTI Diagnostics Inc.

Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186 USA
855.466.8267
www.immucor.com

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. CT:ZZYY-B9EB

Application Number: 0915-22

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Immucor GTI Diagnostics, Inc, located at 20925 Crossroads Circle, Waukesha, WI 53186, USA, manufactured the following product(s):

Product Name

LIFECODES HLA-A SSO Typing Kit
LIFECODES HLA-A eRES SSO Typing Kit
LIFECODES HLA-B SSO Typing Kit
LIFECODES HLA-B eRES SSO Typing Kit
LIFECODES HLA-C eRES SSO Typing Kit
LIFECODES HLA-DRB1 SSO Typing Kit
LIFECODES HLA-DRB1 eRES SSO Typing Kit
LIFECODES HLA-DRB3,4,5 Typing Kit
LIFECODES HLA-DQA1/B1 SSO Typing Kit
LIFECODES HLA-DPA1/B1 SSO Typing Kit
MATCH IT! DNA Software

The product(s) described above and the plant(s) where it is produced are subject to the jurisdiction of the FDA under the Federal, Food, Drug, and Cosmetic Act.

It is certified that the above listed product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last inspection showed that the plant(s) at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Signature_____

Robert A. Sausville
Director
Division of Case Management
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
Food and Drug Administration

This certificate is valid from April 21, 2022 to April 20, 2024.

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. CT:9A6S-YYB8

Application Number: 0905-22

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Immucor GTI Diagnostics, Inc, located at 20925 Crossroads Circle, Waukesha, WI 53186, USA, manufactured the following product(s):

Product Name
LIFECODES LSA Class I
LIFECODES LSA Class II
LIFECODES Class I ID
LIFECODES Class II IDv2
LIFECODES LifeScreen Deluxe
MATCH IT! Antibody
PakPlus
ThromboType1

The product(s) described above and the plant(s) where it is produced are subject to the jurisdiction of the FDA under the Federal, Food, Drug, and Cosmetic Act.

It is certified that the above listed product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last inspection showed that the plant(s) at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Signature_____

Robert A. Sausville
Director
Division of Case Management
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
Food and Drug Administration

This certificate is valid from March 30, 2022 to March 29, 2024.

IMMUCOR

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)

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

EC Authorized Representative: **Immucor Medizinische Diagnostik GmbH**
Robert-Bosch-Straße 32
63303 Dreieich
Germany
Phone: (+49) (0) 6103 80560
Fax: (+49) (0) 6103 8056199

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

Leon Lambry
Senior Director, Quality and Regulatory Affairs
Immucor GTI Diagnostics, Inc.
Waukesha, WI USA

Issue Date: 03 May 2022

Appendix

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

Classification: Annex II, List B

LIFECODES HLA-A SSO Typing Kit (628911)
LIFECODES HLA-A eRES SSO Typing Kit (628913)
LIFECODES HLA-B SSO Typing Kit (628915)
LIFECODES HLA-B eRES SSO Typing Kit (628917)
LIFECODES HLA-DRB1 SSO Typing Kit (628923)
LIFECODES HLA-DRB1 eRES SSO Typing Kit (628925)
LIFECODES HLA-DRB 3,4,5 SSO Typing Kit (628927)
LIFECODES HLA Null Allele SSO Typing Kit (628939)

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

Dilution Solution (628515UDI)

Conformity Assessment for Annex IV and Annex II, List B in vitro diagnostic medical devices performed by:

TÜV Rheinland LGA Products GmbH (0197)
Tillystraße 2
90431 Nürnberg
Germany
Phone: +49 (0) 9116555225
Fax: +49 (0) 9116555226

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
- EN 13612:2002/AC:2003 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)

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

EC Authorized Representative: **Immucor Medizinische Diagnostik GmbH**
Robert-Bosch-Straße 32
63303 Dreieich
Germany
Phone: (+49) (0) 6103 80560
Fax: (+49) (0) 6103 8056199

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

DocuSigned by Leon Lambry
Leon Lambry | I approve this document
30-Jun-2022 | 5:55:58 PM EDT
E3B56F1C8AF764A3682C4262594E6953A

Issue Date: 30-Jun-2022

Leon Lambry
Senior Director, Quality and Regulatory Affairs
Immucor GTI Diagnostics, Inc.
Waukesha, WI USA

Appendix

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

LIFECODES LSA Class I Kit (265100)
LIFECODES LSA Class II Kit (265200)

Wash Buffer (628211)

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1804149-1

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

Products: Annex II List B Products:

LIFECODES HLA-A SSO Typing Kit
LIFECODES HLA-A eRES SSO Typing
LIFECODES HLA-B SSO Typing Kit
LIFECODES HLA-B eRES SSO Typing
LIFECODES HLA-DRB1 SSO Typing kit
LIFECODES HLA-DRB1 eRES SSO Typing kit
LIFECODES HLA-DRB 3,4,5 SSO Typing kit
LIFECODES HLA-Null Allele SSO Typing kit

State of Wisconsin County of Waukesha
I certify that this is a true and correct copy of a document in the possession of Anna Rachfalska which was copied on December 20, 2022.
Notary _____
Notary's expiration date: March 28, 2025

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 1111325-10

Effective date: 2020-12-17

Expiry date: 2025-05-26

Issue date: 2022-05-10

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland®

Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.