Obelis SA
European Authorized Representative Center

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: IO 2045-2013

Order No.: IO 1490-2013

Date: 26/09/2013

THIS IS TO CERTIFY THAT, ACCORDING TO THE EUROPEAN COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

SEEN by the Brussels Chamber of Commerce
Evelien Jonckheere
Brussels, the 02 OCT. 2013

NAME: DNA-TECHNOLOGY, RESEARCH & PRODUCTION, LLC,

ADDRESS: 142281, MOSCOW REGION, PROTVINO, ZHELEZNODOROZHNAYA STR., 20, RUSSIA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 10/09/2013 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
02 -10- 2013
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (1 PAGE, 4 DEVICES)

As of the 11/09/2013, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- place these devices in the Territory of Belgium and the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

OBELIS s.a. - O.E.A.R.C
Registered address :
Bd Général Wahis 53
1030 Bruxelles
G.Elkayam CEO T: +32 2 732 59 54 - Fax +32 2 732 60 03

Mr. G. Elkayam CEO Obelis sa	Brussels Enterprise Commerce & Industry
date & stamp	date & stamp

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.) and ISO 9001-2008 certified in accordance to the profession of a European Authorized Representative.

*and provided that the product classification will not be rejected by the Competent Authorities

Corporate Offices Bd. Général Wahis 53 - 1030 Brussels | Registered Office Av. de Tervueren 34 B42 - 1040 Brussels - Belgium
T: + 32 (0) 2 732 5954 I F: + 32 (0) 2 732 6003 I Email: mail@obelis.net

Ref. No.: IO 2045 - 2013
Order No.: IO 1490 - 2013

Annex A* - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

No.	Generic Device Term	Commercial name	Class**	Catalogue reference number	Short description and intended use	GMDN/EDMS code***
1	Detecting thermocycler/PCR-Diagnostics	DTprime	neither A nor B according to annex II IVD 98/79/EC	O-DTPRIME4M1-EU O-DTPRIME4X1-EU O-DTPRIME4M3-EU O-DTPRIME4M6-EU O-DTPRIME5M1-EU O-DTPRIME5X1-EU O-DTPRIME5M3-EU O-DTPRIME5M6-EU	Detecting thermocyclers DTprimeXXX is intended use for in-vitro diagnostics of using PCR method.	48031
2	Detecting thermocycler/PCR-Diagnostics	DTlite	neither A nor B according to annex II IVD 98/79/EC	O-DTLITE4S1-EU O-DTLITE4S2-EU O-DTLITE4L1-EU O-DTLITE5S1-EU O-DTLITE5S2-EU O-DTLITE5L1-EU	Detecting thermocyclers DTliteXXX is intended use for in-vitro diagnostics of using PCR method.	48031
3	Fluorescent detector /PCR-Diagnostics	Gene-4	neither A nor B according to annex II IVD 98/79/EC	O-GENE4-EU	Fluorescent detector of a polymerase chain reaction is a special instrument to evaluate fluorescent radiation of light of a reactionary mixture in test tubes directly after finishing a polymerase chain reaction (PCR).	26.03.10.01
4	Real-time PCR Kit/PCR-Diagnostics	FEMOFLOR	neither A nor B according to annex II IVD 98/79/EC	R1-P801-S3/6EU R1-P802-S3/5EU R1-P803-S3/4EU	The FEMOFLOR® Real-time PCR Kit aimed to improve the efficiency of current diagnostic tools used for identification of female genital infections.	48208

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under his/her responsibility (IVD 98/79/EC).

*** GMDN or EDMS codes are mandatory information to complete the Notification.

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
02 -10- 2013
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

Manufacturer's Name «DNA-Technology, Research&Production», LLC — **Signature:** _____ **Date:** 27.05.2013 — **Stamp:**

Obelis S.A. — **Signature:** G.ELKAYAM, C.E.O. — **Date:** 30/9/2013 — **Stamp:**

Signature: _____ **Date:** _____ **Stamp:**

OBELIS s.a. - O.E.A.R.C
Registered address :
Bd Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

Obelis SA
European Authorized Representative Center

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: IU 4244-2015

Order No.: IU 3948-2015

BELGIUM

Date: 31/08/2015

THIS IS TO CERTIFY THAT, ACCORDING TO THE EUROPEAN COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: DNA-TECHNOLOGY, RESEARCH&PRODUCTION LLC

ADDRESS: 142281, MOSCOW REGION, PROTVINO, ZHELEZNODOROZHNAYA STREET 20, RUSSIA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 25/08/2015 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (2 PAGES, 8 DEVICES)

As of the 26/08/2015 and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the Territory of Belgium and the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
03 -09- 2015
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

OBELIS s.a. - O.E.A.R.C
Registered address :
Bd Général Wahis 53
1030 Bruxelles
Tel +32 2 732 59 54 - Fax +32 2 732 60 03

SEEN
by the Brussels Chamber of Commerce

G.ELKAYAM C.E.O

Mr. G. Elkayam CEO
Obelis sa
date & stamp

Evelien Jonckheere
Brussels Enterprise Commerce & Industry
Brussels, the 03 SEP 2015
date & stamp

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.) and ISO 9001-2008 certified in accordance to the profession of a European Authorized Representative.

Corporate Offices Bd. Général Wahis 53 - 1030 Brussels I Registered Office Av. de Tervueren 34 B44 - 1040 Brussels - Belgium
T: + 32 (0) 2 732 5954 I F: + 32 (0) 2 732 6003 I Email: mail@obelis.net

*and provided that the product classification will not be rejected by the Competent Authorities.

Ref. No.:IU4244-2015
Order No.:IU3948-2015

Annex A* - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

No.	Generic Device Term	Commercial name	Class**	Catalogue reference number	Short description and intended use	GMDN/ EDMS code***
1	PCR Kit/PCR-Diagnostics	Hypertension Susceptibility REAL-TIME PCR Genotyping Kit	All others	R1-H902-N3/4EU	The Hypertension Susceptibility REAL-TIME PCR Genotyping Kit is designed to detect and discriminate nine genetic polymorphisms associated with hypertension (OMIM #145500) with an aid of Polymerase Chain Reaction (PCR) method.	16.01.04.90
2	PCR Kit/PCR-Diagnostics	Thrombophilia Susceptibility REAL-TIME PCR Genotyping Kit	All others	R1-H901-N3/4EU	The Thrombophilia Susceptibility REAL-TIME PCR Genotyping Kit is designed to detect and discriminate eight genetic polymorphisms associated with thrombophilia blood clotting disorders (OMIM #188050; #188055; #227500; #613235; #187800) with an aid of Polymerase Chain Reaction (PCR) method.	16.01.04.90
3	PCR Kit/PCR-Diagnostics	Folate Metabolism REAL-TIME PCR Genotyping Kit	All others	R1-H908-N3/4EU	The Folate Metabolism REAL-TIME PCR Genotyping Kit is designed to detect and discriminate four genetic polymorphisms associated with folic acid metabolism disturbances (OMIM #236250; #250940; #236270) with an aid of Polymerase Chain Reaction (PCR) method.	16.01.04.90
4	PCR Kit/PCR-Diagnostics	Warfarin Pharmacogenetics REAL-TIME PCR Genotyping Kit	All others	R1-H904-N3/4EU	The Warfarin Pharmacogenetics REAL-TIME PCR Genotyping Kit is designed to detect and discriminate nine genetic polymorphisms associated with warfarin anticoagulant resistance (OMIM #122700) with an aid of Polymerase Chain Reaction (PCR) method.	16.01.04.90
5	PCR Kit/PCR-Diagnostics	BRCA mutations REAL-TIME PCR Genotyping Kit	All others	R1-H927-N3/4EU	The BRCA mutations REAL-TIME PCR Genotyping Kit is designed to detect and discriminate eight genetic polymorphisms associated with breast cancer (OMIM #604370; #601555) with an aid of Polymerase Chain Reaction (PCR) method.	16.01.04.90

CHAMBRE DE COMMERCE ET D'INDUSTRIE BRUXELLES
03-09-2015
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

G.ELKAYAM C.E.O.

OBELIS s.a. Anti-Counterfeiting Lab.

6	PCR Kit/PCR-Diagnostics	IL28B REAL-TIME PCR Genotyping Kit	All others	R1-H930-N3/4EU	The IL28B REAL-TIME PCR Genotyping Kit is designed to detect and discriminate two genetic polymorphisms associated with susceptibility to hepatitis C virus (OMIM #609532) with an aid of Polymerase Chain Reaction (PCR) method.	16.01.04.90
7	PCR Kit/PCR-Diagnostics	Lactose Intolerance REAL-TIME PCR Genotyping Kit	All others	R1-H941-N3/4EU	The Lactose Intolerance REAL-TIME PCR Genotyping Kit is designed to detect and discriminate one genetic polymorphism associated with adult type hypolactasia (OMIM #223100) with an aid of Polymerase Chain Reaction (PCR) method.	16.01.04.90
8	PCR Kit/PCR-Diagnostics	Hemochromatosis REAL-TIME PCR Genotyping Kit	All others	R1-H939-N3/4EU	The Hemochromatosis REAL-TIME PCR Genotyping Kit is designed to detect and discriminate three genetic polymorphisms associated with hereditary hemochromatosis (OMIM #235200) with an aid of Polymerase Chain Reaction (PCR) method.	16.01.04.90

* Annex A is part of the Agreement.
** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

*** GMDN or EDMS codes are mandatory information to complete the Notification.

Manufacturer's Name «DNA-Technology, Research&Production», LLC

Signature: _____

Date: 22.04.2015

Stamp:

Obelis S.A.

Signature: G.ELKAYAM CEO

Date: 31/8/2015

Stamp:

BECI

Signature: _____

Date: _____

Stamp:

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
03 -09- 2015
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

OBELIS s.a. - O.E.A.R.C
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Obelis SA
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER
Obelis
SINCE 1988

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: MC 5223-2017

Order No.: MC 4840-2016

BELGIUM

Date: 12/01/2017

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: "DNA-TECHNOLOGY, RESEARCH & PRODUCTION", LLC

ADDRESS: 142281, 20 ZHELEZNODOROZHNAYA STREET,
PROTVINO, MOSCOW REGION,
RUSSIA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostic medical devices, as stipulated here above, are fulfilling the applicable requirements of the Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 14/12/2016 in compliance with the Council Directive 98/79/EC - article 10 requirements.

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (4 PAGES, 12 DEVICES)

As of the 15/12/2016, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the EU and EEA territory.

G.ELKAYAM CEO

Mr. G. Elkayam, CEO
Obelis sa
date & stamp

OBELIS s.a. - O.E.A.R.C
Registered address :
Bd Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

EAR

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001:2008 and ISO 13485:2003 certified in accordance to the profession of a European Authorized Representative.

*and provided that the product classification will not be rejected by the Competent Authorities.

CE

Ref. No.: MC 5223-2017
Order No.: MC 4840-2016

Annex A* - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

No.	Catalogue reference number	Commercial name	Generic Device Term	Short description and intended use	GMDN/EDMS code	Class**
1	R1-P205-23/9EU R1-P205-S3/9EU R1-P205-24/9EU F1-P205-51/1EU F1-P205-21/1EU	EBV	PCR Kit/PCR-Diagnostics	The EBV REAL-TIME PCR Detection Kit and EBV FLASH PCR Detection Kit are intended for research and diagnostic applications. The EBV REAL-TIME PCR Detection Kit and EBV FLASH PCR Detection Kit are an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The EBV REAL-TIME PCR Detection Kit and EBV FLASH PCR Detection Kit are designed to detect Epstein Barr virus nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	49653	All others
2	R1-P201-23/9EU R1-P201-S3/9EU R1-P201-24/9EU F1-P201-51/1EU F1-P201-21/1EU	HSV 1, 2	PCR Kit/PCR-Diagnostics	The HSV 1, 2 REAL-TIME PCR Detection Kit and HSV 1, 2 FLASH PCR Detection Kit are intended for research and diagnostic applications. The HSV 1, 2 REAL-TIME PCR Detection Kit and HSV 1, 2 FLASH PCR Detection Kit are an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The HSV 1, 2 REAL-TIME PCR Detection Kit and HSV 1, 2 FLASH PCR Detection Kit are designed to detect Herpes symplex virus 1, 2 nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	49539	All others
3	R1-P315-S3/4EU	HPV-QUANT-4	PCR Kit/PCR-Diagnostics	The HPV-QUANT-4 quantitative PCR Detection Kit is intended for research and diagnostic applications. The HPV-QUANT-4 quantitative PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The HPV-QUANT-4 quantitative PCR Detection Kit is intended for the specific identification and quantification of low-risk (HPV 6,11) and high-risk (HPV 16,18) in regard to their oncogenic properties human papillomaviruses nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	49994	All others

G.EL KAYAM C.E.O.

4	R1-P317-S3/5EU	HPV-QUANT-21	PCR Kit/PCR-Diagnostics	The HPV-QUANT-21® quantitative PCR Detection Kit is intended for research and diagnostic applications. The HPV-QUANT-21® quantitative PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The HPV-QUANT-21® quantitative PCR Detection Kit is intended for the specific identification and quantification of low-risk (HPV 6, 11, 44) and high-risk (HPV 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82) in regard to their oncogenic properties human papillomaviruses nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	49994	All others
5	R1-P403-23/4EU R1-P403-S3/4EU R1-P403-24/4EU F1-P403-51/2EU F1-P403-21/2EU	Legionella pneumophila	PCR Kit/PCR-Diagnostics	The Legionella pneumophila PCR Detection Kit is intended for research and diagnostic applications. The Legionella pneumophila PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Legionella pneumophila PCR Detection Kit is designed to detect Legionella pneumophila nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	51060	All others
6	R1-P404-23/4EU R1-P404-S3/4EU R1-P404-24/4EU F1-P404-51/2EU F1-P404-21/2EU	M. tuberculosis – M. bovis	PCR Kit/PCR-Diagnostics	The M. tuberculosis – M. bovis REAL-TIME PCR Detection Kit and M. tuberculosis – M. bovis FLASH PCR Detection Kit are intended for research and diagnostic applications. The Kits are an in vitro Nucleic Acid Test (NAT) – based pathogen detection products. The Kits are designed to detect Mycobacterium tuberculosis and Mycobacterium bovis nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	51149	All others
7	R1-P206-23/4EU R1-P206-S3/4EU R1-P206-24/4EU F1-P206-51/2EU F1-P206-21/2EU	VZV	PCR Kit/PCR-Diagnostics	The VZV REAL-TIME PCR Detection Kit and VZV FLASH PCR Detection Kit are intended for research and diagnostic applications. The Kits are	47291	All others

				an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Kits are designed to detect Varicella zoster virus nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.		
8	R1-H801-S3/5EU	AZF Microdeletions	PCR Kit/PCR-Diagnostics	The AZF Microdeletions REAL-TIME PCR Genotyping Kit is intended for research and diagnostic applications. The AZF MicrodeletionsREAL-TIME PCR Genotyping Kit is in vitro Nucleic Acid Test (NAT) – based human genotyping product. The AZF MicrodeletionsREAL-TIME PCR Genotyping Kit is intended for detection of AZF locus deletions which are the common cause of male infertility defined by loss of spermatozoids motion ability (azoospermia) with an aid of Polymerase Chain Reaction (PCR) method.	16.01.04.90	All others
9	R3-P408-23/4EU R3-P408-S3/4EU	Influenza A virus (subtype H1N1)	PCR Kit/PCR-Diagnostics	The Influenza A virus (subtype H1N1) PCR Detection Kit is intended for research and diagnostic applications. The Influenza A virus (subtype H1N1) PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Influenza A virus (subtype H1N1) PCR Detection Kit is designed to detect Influenza A virus (subtype H1N1) nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	49165	All others
10	R1-P316-S3/4EU	HPV-QUANT-15	PCR Kit/PCR-Diagnostics	The HPV-QUANT-15 quantitative PCR Detection Kit is intended for research and diagnostic applications. The HPV-QUANT-15 quantitative PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The HPV-QUANT-15® quantitative PCR Detection Kit is intended for the the specific identification and quantification of low- and high-risk (in regard to oncogenic properties) human papillomaviruses including: low-risk HPV types 6 and 11 without differentiation high-risk HPV types 16, 31,	49994	All others

				33, 35, 52, 58 without differentiation HPV types 18, 39, 45, 59 without differentiation HPV type 56 HPV type 51 HPV type 68 in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.		
11	R3-P409-23/4EU R3-P409-S3/4EU	Influenza A virus	PCR Kit/PCR-Diagnostics	The Influenza A virus PCR Detection Kit is intended for research and diagnostic applications. The Influenza A virus PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Influenza A virus PCR Detection Kit is designed to detect Influenza A virus nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	49161	All others
12	R3-P410-23/4EU R3-P410-S3/4EU	Influenza B virus	PCR Kit/PCR-Diagnostics	The Influenza B virus PCR Detection Kit is intended for research and diagnostic applications. The Influenza B virus PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Influenza B virus PCR Detection Kit is designed to detect Influenza B virus nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.	49205	All others

* Annex A is part of the Agreement
** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

Manufacturer's Name «DNA-Technology, Research&Production», LLC

Signature: _____

Date: 15.12.2016

Stamp:

"Научно-производственное объединение ДНК-Технология"

Obelis S.A.

Signature: G.ELKAYAM C.E.O.

Date: 16/1/2017

Stamp:

OBELIS s.a. - O.E.A.R.C
Registered address :
Bd Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

CERTIFICATE OF IVD NOTIFICATION

Ref. No.: GR 1922-2021

Order No.: LM 2003-2021

Belgium

Date: 27/07/2021

This is to certify that, according to the Council Directive 98/79/EC, Obelis s.a. (O.E.A.R.C.) performed all notification duties and responsibilities as the European Authorized Representative (EC REP) of:

name:	DNA-Technology, Research & Production, LLC
Address:	20 Zheleznodorozhnaya Street Protvino, Moscow Region 142281, Russia

as stipulated and demanded by the aforementioned directive.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 27/07/2021 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

In-vitro diagnostic medical devices: Please See Annex A - List of Devices (6 pages, 10 Devices)

As of the 28/07/2021, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

G. ELKAYAM C.E.O

Obelis s.a. - O.E.A.R.C.
Registered Address
Bld Général Wahis 53
1030 Bruxelles
Tel: +32.2.732.59.54 - Fax: +32.2.732.60.03

Mr. G. Elkayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

* This is not a CE mark and is only provided as a template for informational purposes.

** This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

Order No.: GR 1922-2021
Ref No.: LM 2003-2021

Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN/ EDMS Code	Class
1.	P-910-1/1EU	STOR-M transport medium	General specimen container IVD, additive/medium	The STOR-M transport medium is intended for transport and storage of human biological samples (scrapes/swabs of epithelial cells from urogenital tract, oropharynx, nasopharynx, rectum, skin, conjunctiva of the eye), including those containing an impurity of mucus, followed by nucleic acids analysis (human and microbial DNA, viral RNA) by polymerase chain reaction method.	63232	neither A or B according II IVD 98/79/EC
2.	P-001/1EU P-021/4EU	PREP-RAPID DNA Extraction Kits	Nucleic acid extraction/isolation kit IVD	The PREP-RAPID DNA Extraction Kit is intended for DNA extraction from biological materials (saliva, urine, prostatic fluid, cerebrospinal fluid, epithelial cells scrapes from posterior pharyngeal wall, urethra, cervical canal, posterior vaginal vault etc.) for further analysis by polymerase chain reaction (PCR). The PREP-RAPID Genetics DNA Extraction Kit is intended for DNA extraction from whole peripheral blood for further DNA genetic testing by PCR.	52521	neither A or B according II IVD 98/79/EC

3.	P-002/1EU P-002/2EU	PREP-NA DNA/RNA Extraction Kits	Nucleic acid extraction/isolation kit IVD	The PREP-NA and PREP-NA PLUS DNA/RNA Extraction Kits are intended for DNA/RNA extraction from biological materials for further analysis with reverse transcription (RNA) and/or polymerase chain reaction (DNA). In the PREP-NA PLUS DNA/RNA Extraction Kit the total volume of purified DNA/RNA is larger comparing to standard PREP-NA DNA/RNA Extraction Kit (50 µL) for more PCR tests.	52521	neither A or B according II IVD 98/79/EC
4.	P-007-N/1EU	PREP-NA-S DNA/RNA Extraction Kit	Nucleic acid extraction/isolation kit IVD	The ***PREP-NA-S* DNA/RNA Extraction Kit** is intended for fast NA extraction from biological materials for further analysis by RT-PCR (PCR with Reverse Transcription)/PCR (polymerase chain reaction). The ***PREP-NA-S* DNA/RNA Extraction Kit** is designed to extract NA from biological materials: nasopharyngeal, oropharyngeal swabs.	52521	neither A or B according II IVD 98/79/EC
5.	P-003/1EU, P-003/2EU, P-023/4EU	PREP-GS DNA Extraction Kits	Nucleic acid extraction/isolation kit IVD	The PREP-GS and PREP-GS PLUS DNA Extraction Kits are intended for DNA extraction from biological materials for further analysis by polymerase chain reaction (PCR). In the PREP-GS PLUS DNA Extraction Kit the total volume of purified DNA is larger comparing to standard PREP-GS DNA Extraction Kit for more PCR tests. The PREP-GS Genetics DNA Extraction Kit is intended for DNA extraction from whole peripheral blood for further DNA genetic testing by PCR.	52521	neither A or B according II IVD 98/79/EC

	R1-P023-S3/5EU	MycosoScreen REAL-TIME PCR Detection Kit	Multiple fungi/yeast species nucleic acid IVD, kit	The ***MycosoScreen* REAL-TIME PCR Detection Kit** is intended for detection and typing of fungal infectious agents from genus Candida, Malassezia, Saccharomyces and Debaryomyces: Meyerozyma guilliermondii (C. guilliermondii), Candida albicans, Pichia kudriavzevii (C.krusei), Saccharomyces cerevisiae, Candida auris, Candida tropicalis, Clavispora lusitaniae (C.lusitaniae), Debaryomyces hansenii (C.famata), Candida dubliniensis, Candida glabrata, Candida parapsilosis, Malassezia spp., Kluyveromyces marxianus (C.kefyr), Malassezia furfur. Samples are human biological material (blood, phlegm, urine, swabs/scrapes from respiratory tract, gastrointestinal and urogenital tracts, faeces, bioptates), catheter and endotracheal tube washings, and fungal cultures.	51973	neither A or B according II IVD 98/79/EC

	R1-H004-23/4EU, R1-H004-S3/4EU, R1-H004-N3/4EU	HLA-B27 REAL-TIME PCR Genotyping Kit	HLA-B27 genotyping IVD, kit, nucleic acid technique (NAT)	The HLA-B27 REAL-TIME PCR Genotyping Kit is intended for rapid group-specific detection of HLA-B27 alleles (major histocompatibility complex, class I, B) by Real-Time PCR method. Samples are human biological materials: peripheral blood. These alleles are generally recognized as a genetic marker of multiple disease conditions e.g. rheumatoid arthritis and ankylosing spondylitis (Bekhterev's disease). Indications for the use: - the presence of clinical symptoms of spondyloarthropathies: inflammatory back pain, asymmetric peripheral oligoarthritis, mainly of the lower extremities, enteritis and/or tendosynovitis; - as an additional laboratory indicator for predicting the severity of spondyloarthropathies	65537	neither A or B according II IVD 98/79/EC
	R1-P501-S3/9EU, R1-P501-23/9EU R1-P501-UA/9EU	Helicobacter pylori REAL-TIME PCR Detection Kit	Helicobacter pylori nucleic acid IVD, kit, nucleic acid technique (NAT)	The Helicobacter pylori REAL-TIME PCR Detection Kit is designed to detect Helicobacter pilory DNA in human biological samples with an aid of Polymerase Chain Reaction (PCR) method. Samples are human biological materials: bioptates, faeces.	51000	neither A or B according II IVD 98/79/EC

	R1-P028-S3/6EU	BacScreen OM REAL-TIME PCR Detection Kit	Multiple-bacteria-genus IVDs	The ***BacScreen OM* REAL-TIME PCR Detection Kit** is designed for DNA analysis of opportunistic bacteria from classes Bacilli, Betaproteobacteria and Gammaproteobacteria that cause nosocomial and community-acquired infections with an aid of Polymerase Chain Reaction (PCR) method. Samples are human biological materials (phlegm, urine, swabs/scrapes of epithelial cells from respiratory tract, gastrointestinal tract and urogenital tract, feaces, aspirates, exudates) and bacterial cultures.	63010	neither A or B according II IVD 98/79/EC
	R1-P026-S3/5EU, R1-P027-S3/4EU, R1-P027-23/4EU	BacResista GLA REAL-TIME PCR Detection Kits	Multiple antimicrobial resistance nucleic acid IVD, kit	The BacResista GLA and BacResista Gla Van/Mec REAL-TIME PCR Detection Kits are designed for DNA analysis of bacteria resistant to glycopeptide (G) and beta-lactam (L) antibiotics (A) in DNA material obtained from biological samples and bacterial cultures with an aid of Polymerase Chain Reaction (PCR) method. Samples are human biological materials (phlegm, urine, swabs of epithelial cells from respiratory tract, gastrointestinal tract and urogenital tract, feaces, aspirates, exudates) and bacterial cultures. Indications for the use: the need to study a possible antibiotic resistance in bacteria that caused infectious disease.	60673	neither A or B according II IVD 98/79/EC

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

Obelis s.a.

Signature: _____

Date: _____

Stamp:

G. ELKAYAM
C.E.O.

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CERTIFICATE OF IVD NOTIFICATION

Reference No.: LM 0616-2022

Order No.: EU DF 0310-202

BELGIUM

Date: 13/06/2022

This is to certify that, according to the Council Directive 98/79/EC, Obelis s.a. performed all notification duties and responsibilities as the European Authorized Representative (EC REP) of:

Name: DNA-Technology, Research & Production, LLC

Address: 20 Zheleznodorozhnaya Street
Protvino, Moscow Region
142281, Russia

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The manufacturer declares that the IVD device(s) comply(ies) with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (EC REP) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical device(s), as stipulated here above, is/are fulfilling the applicable requirements of the European Council Directive 98/79/EC on the

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (EC REP) on in compliance with the European Council Directive 98/79/EC - article 10 requirements on the 17/05/2022

IN-VITRO DIAGNOSTIC MEDICAL DEVICE(S): Please See Annex A - List of Devices (9 Devices; 3 Pages)

As of the 18/05/2022 , and provided that the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on this(ese) device(s);

- Place this(ese) device(s) in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).*

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Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.).
Obelis s.a. is ISO 9001 : 2015 and ISO 13485 : 2016 certified.

*This certificate will become void automatically upon termination of the EAR agreement

Ref No.: LM 0616-2022

Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN / GIVD Code	Class and Rule under IVDD
1.	R3-P439-S3/5EU	AVRI Panel Multiplex REALTIME PCR Detection Kit	REAL-TIME PCR Detection Kit	The AVRI Panel Multiplex REAL-TIME PCR Detection Kit is designed to detection of the most common causative agents of acute viral respiratory infections by Real-Time PCR method. Samples are human biological materials: nasopharyngeal swabs, oropharyngeal swabs, bronchoalveolar lavage, endotracheal aspirate, nasopharyngeal aspirate, phlegm.	47922	neither A nor B according II IVD 98/79/EC
2.	R3-P446-S3/9EU	SARS-CoV-2 Lite REAL-TIME PCR Detection Kit	REAL-TIME PCR Detection Kit	The SARS-CoV-2 Lite REALTIME PCR Detection Kit is designed to detect Coronavirus SARS-CoV-2 in human biological samples (nasopharyngeal smears, oropharyngeal smears) with an aid Reverse Transcription (RT) and of Polymerase Chain Reaction (PCR) methods.	64747	neither A nor B according II IVD 98/79/EC
3.	R1-P815-S3/6EU R1-P815-XA/5EU	ENTEROFLOR Kiddy REAL-TIME PCR Detection Kit	REAL-TIME PCR Detection Kit	The ENTEROFLOR Kiddy REAL-TIME PCR Detection Kit is designed for detection of colon associated bacteria DNA (Firmicutes, Proteobacteria, Bacteroidetes, Actinobacteria, Fusobacteria, Verrucomicrobia, Euryarchaeota filums), including Candida fungi, as well as gene of methicillinresistance Staphylococcus spp. (mecA), Cl.difficile with enterotoxins A and B (tcdA, tcdB), Str.agalactiae with invasiveness marker gene (srr2) by real-time PCR in DNA preparations obtained from children's faeces sample.	61058	neither A nor B according II IVD 98/79/EC

4.	P-016-N/2EU P-016-1/2EU P-015-N/2EU	PREP-OPTIMA DNA Extraction Kit	Nucleic acid extraction/ isolation kit IVD	The PREP-OPTIMA DNA Extraction Kit is intended for human, bacterial, viral, and fungal DNA extraction from human biological material (blood; buccal epithelium; smears/scrapings from respiratory, gastrointestinal, and urogenital tracts; urine; faeces; bioptates; amniotic liquid; ejaculate; cerebrospinal fluid; breast milk), as well as for DNA extraction from microbial cultures (bacterial, fungal) received from this biological material for further PCR analysis.	52521	neither A nor B according II IVD 98/79/EC
5.	R1-H958-N3/4EU R1-H959-N3/4EU	Hemostasis F2,F5 mutations REAL-TIME PCR Genotyping Kit	REAL-TIME PCR Detection Kit	The Hemostasis F2, F5 mutations REAL-TIME PCR Genotyping Kit is intended for detection and allelic discrimination of the genetic polymorphisms associated with risk of health complications provided by hormonal contraception use or in case of passing by hormonal replacement therapy. Samples are peripheral blood.	59586	neither A nor B according II IVD 98/79/EC
6.	R1-H806-S3/4EU R1-H806-UA/4EU R1-H807-S3/4EU R1-H807-UA/4EU	EGFR mutations REAL-TIME PCR Genotyping Kit	REAL-TIME PCR Detection Kit	The EGFR mutations REALTIME PCR Genotyping Kit is intended for the detection of somatic mutations in the EGFR gene (deletions and insertions in the 19th exon, insertions in the 20th exon, mutations L858R, T790M, L861Q, S7681 and G719X) by real time PCR in human genomic DNA extracted from formaldehyde-fixed paraffin-embeded (FFPE) non-small-cell lung cancer samples in order to choose the patients for target therapy with tyrosinkinase inhibitors.	58271	neither A nor B according II IVD 98/79/EC
7.	P-028-N/2EU P-030-N/2EU	PREP-PK Kit for sample pretreatment while processing of nucleic acids isolation	Nucleic acid extraction/ isolation kit IVD	The PREP-PK kit is intended for the removal of inhibiting effects causing by fixation and proteolysis by proteinase K in human biomaterial (formaldehyde-fixed paraffinin-embadded (FFPE) tissues, native tissues, cervical swabs taken in fixing transport medium for liquid-based cytology) before nucleic acid extraction for molecular-genetic analysis by PCR method.	42703	neither A nor B according II IVD 98/79/EC

8.	R1-P012-S3/4EU R1-P012-23/4ElJ R1-P012-UA/9EU	Streptococcus agalactiae REAL-TIME PCR Detection Kit	REAL-TIME PCR Detection Kit	The Streptococcus agaiactiae REAL-TIME PCR Detection Kit is intended for Streptococcus agalactiae (group B streptococcus) DNA detection in human biological samples (blood, phlegm, urine, scrapes from respiratory tract, urogenital and gastrointestinal tracts, faeces or meconium, bioptates, cerebrospinal fluid), washings from catheters and endotracheal tubes and bacterial cultures by polymerase chain reaction with detection in real time.	51753	neither A nor B according II IVD 98/79/EC
9.	R1-P101-23/9EU R1-P101-S3/9EU R1-P101-UA/9EU	Chlamydia trachomatis REAL-TIME PCR Detection Kit	REAL-TIME PCR Detection Kit	The Chlamydia trachomatis REAL-TIME PCR Detection Kit is designed to detect Chlamydia trachomatis nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method. Samples are human biological materials: urine, prostate fluid, ejaculate, scrapings of epithelial cells (from the urogenital tract, oropharynx, rectum, conjunctiva of the eye).	47320	B, according II IVD 98/79/EC

*Annex A is part of the Agreement.
** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

Obelis s.a.

Date: 13/06/2022

Stamp

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CERTIFICATE OF IVD NOTIFICATION

Reference No.: LM 0620-2022

Order No.: EU DF 0480-2022

BELGIUM

Date: 13/06/2022

This is to certify that, according to the Council Directive 98/79/EC, Obelis s.a. performed all notification duties and responsibilities as the European Authorized Representative (EC REP) of:

Name: DNA-Technology, Research & Production, LLC

Address: 20 Zheleznodorozhnaya Street
Protvino, Moscow Region
142281, Russia

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The manufacturer declares that the IVD device(s) comply(ies) with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (EC REP) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical device(s), as stipulated here above, is/are fulfilling the applicable requirements of the European Council Directive 98/79/EC on the

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (EC REP) on in compliance with the European Council Directive 98/79/EC - article 10 requirements on the 17/05/2022

IN-VITRO DIAGNOSTIC MEDICAL DEVICE(S): Please See Annex A - List of Devices (10 Devices; 2 Pages)

As of the 18/05/2022 , and provided that the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on this(ese) device(s);

- Place this(ese) device(s) in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).*

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Mr. G. Elkayam CEO
Obelis sa

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Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.).
Obelis s.a. is ISO 9001 : 2015 and ISO 13485 : 2016 certified.

*This certificate will become void automatically upon termination of the EAR agreement

Order No.: EU DF 0480-2022
Ref No.: LM 0620-2022

Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN / GIVD Code	Class and Rule under IVDD
1.	R1-P029-S3/6EU R1-P029-XA/5EU	BacScreen Pneumo REALTIME PCR Detection Kit	REAL-TIME PCR Detection Kit	BacScreen Pneumo REAL-TIME PCR Detection Kit is designed for DNA analysis of bacteria from classes Bacilli, Betaproteobacteria, Chlamydia, Gammaproteobacteria and Mollicutes causing respiratory nosocomial and communityacquired infections and their complications (sepsis), in human biological material (sputum, aspirates, bioptates, exudates, smears/scrapes, washings from respiratory tract), bacterial cultures from this biomaterial and hemocultures, by real-time polymerase chain reaction.	58957	Neither A nor B according II IVD 98/79/EC
2	R1-H803-S3/9EU R1-H803-23/9EU R1-H803-UA/9EU	Fetal Gender REAL-TIME PCR Detection Kit	REAL-TIME PCR Detection Kit	Fetal Gender REAL-TIME PCR Detection Kit is intended for the detection of multi-copy fragment of Y chromosome in samples of cell-free fetal DNA extracted from the blood of pregnant women by Real-Time PCR method.	60003	Neither A nor B according II IVD 98/79/EC
3	R1-H802-S3/9EU R1-H802-23/9EU	Fetal RHD Genotyping REAL-TIME PCR Kit	REAL-TIME PCR Detection Kit	Fetal RHD Genotyping REALTIME PCR Kit is designed to detect cell-free fetal DNA of RHD gene in the blood of Rhdnegative pregnant women with an aid of Polymerase Chain Reaction (PCR) method in order to predict the risk of Rh-disease and hemolytic disease of the fetus and newborn.	60103	Neither A nor B according II IVD 98/79/EC
4	R1-H810-S3/9EU R1-H810-23/9EU	NeoScreen SMA/TREC/ KREC REAL-TIME PCR Detection Kit	REAL-TIME PCR Detection Kit	NeoScreen SMA/TREC/KREC REAL-TIME PCR Detection Kit is designed to detect homozygous deletion of exon 7 of the SMNI gene and assess the content of T cell receptor excision circles (TREC) and kappadeleting recombination excision circle (KREC) in newborn biological material (whole blood, dried blood spots) for screening for spinal muscular atrophy and primary	59089	Neither A nor B according II IVD 98/79/EC

				immunodeficiencies by real-time PCR		
5	P-029-N/2EU	PREP-CITO DBS DNA Extraction Kit	REAL-TIME PCR Detection Kit	The PREP-CITO DBS DNA Extraction Kit is intended for human genomic DNA extraction from dried blood spots (DBS) for further analysis with polymerase chain reaction (PCR)	52521	Neither A nor B according II IVD 98/79/EC
6	P-119-A/9EU P-119-N/9EU P-119-P/9EU P-120-P/9EU P-121-P/9EU	PREP-MB DWP DNA/RNA Extraction Kit	REAL-TIME PCR Detection Kit	PREP-MB DWP DNA/RNA Extraction Kit is designed to extract NA from biological materials: nasopharyngeal, oropharyngeal swabs	52521	Neither A nor B according II IVD 98/79/EC
7	P-103-N/4EU P-103-A/8EU	PREP-MB MAX DNA Extraction Kit	REAL-TIME PCR Detection Kit	PREP-MB MAX DNA Extraction Kit is intended for human, bacterial, viral, and fungal DNA extraction from human biological material (whole peripheral blood; smears/scrapings from urogenital tract and rectum; urine; ejaculate; milk; faeces) for further PCR analysis.	52521	Neither A nor B according II IVD 98/79/EC
8	P-027/2EU	PREP-NA-FET DNA Extraction Kit	REAL-TIME PCR Detection Kit	The PREP-NA-FET DNA Extraction Kit is intended for fetal DNA purification from peripheral blood of pregnant women.	52521	Neither A nor B according II IVD 98/79/EC
9	P-901-1/1EU P-901-R/1EU P-901-N/1EU	STOR-F transport medium	REAL-TIME PCR Detection Kit	The STOR-F transport medium is intended for transport and storage of human biological samples (scrapes/smears of epithelial cells from urogenital tract, oropharynx, nasopharynx, rectum, skin, conjunctiva of the eye) followed by nucleic acids analysis (human DNA, DNA of microorganisms, RNA of viruses) by polymerase chain reaction method	63232	Neither A nor B according II IVD 98/79/EC
10	R1-P204-S3/9EU R1-P204-23/9EU, R1-P204-UA/9EU	CMV REAL-TIME PCR Detection Kit	REAL-TIME PCR Detection Kit	CMV REAL-TIME PCR Detection Kit is designed to detect CMV nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method	30798	B, according II IVD 98/79/EC

*Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility

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Date: 13/06/2022

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

"DNA-Technology, Research&Production", LLC
Address:142281, Moscow region, Protvino, Zheleznodorozhnaya street, 20
Country: Russia

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

List of Products

No	Code No.	Name
1	O-DTPRIME4M1-EU O-DTPRIME4X1-EU O-DTPRIME4M3-EU O-DTPRIME4M6-EU O-DTPRIME5M1-EU O-DTPRIME5X1-EU O-DTPRIME5M3-EU O-DTPRIME5M6-EU	DTprime
2	O-DTLITE4S1-EU O-DTLITE4S2-EU O-DTLITE4L1-EU O-DTLITE5S1-EU O-DTLITE5S2-EU O-DTLITE5L1-EU	DTlite
3	O-GENE4-EU	Gene-4
4	R1-P801-S3/6EU R1-P802-S3/5EU R1-P803-S3/4EU	FEMOFLOR

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).

- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

- ISO 9001:2015;
- ISO 13485:2016.

Corporate Contact Information

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Mr. Vladimir Dmitrovskiy
Position: General Director

Signature:

Date 27 July 2019

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European Authorized Representative:
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Fax: 32.2.732.60.03
E-mail: mail@obelis.net
Representative: Mr. Gideon ELKAYAM (CEO)

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

"DNA-Technology, Research&Production", LLC
Address:142281, Moscow region, Protvino, Zheleznodorozhnaya street, 20
Country: Russia

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

- *Please refer to the attached Annex to Declaration of Conformity*

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:
- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

- ISO 9001: 2015
- ISO 13485:2016

Corporate Contact Information

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Mr. Vladimir Dmitrovskiy
Position: General Director

Signature: _____

Date : 29 July 2019

Stamp

European Authorized Representative:
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Representative: Mr. Gideon ELKAYAM (CEO)

Annex to EC Declaration of Conformity

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

No.	Generic Device Term	Commercial name	Class **	Catalogue reference number	Short description and intended use
1	PCR Kit/PCR-Diagnostics	Hypertension Susceptibility REAL-TIME PCR Genotyping Kit	All others	R1-H902-N3/4EU	The Hypertension Susceptibility REAL-TIME PCR Genotyping Kit is designed to detect and discriminate nine genetic polymorphisms associated with hypertension (OMIM #145500) with an aid of Polymerase Chain Reaction (PCR) method. The kit contains: PCR mix, PCR buffer, Taq-AT-polymerase, Mineral oil
2	PCR Kit/PCR-Diagnostics	Thrombophilia Susceptibility REAL-TIME PCR Genotyping Kit	All others	R1-H901-N3/4EU	The Thrombophilia Susceptibility REAL-TIME PCR Genotyping Kit is designed to detect and discriminate eight genetic polymorphisms associated with thrombophilia blood clotting disorders (OMIM #188050; #188055; #227500; #613235; #187800) with an aid of Polymerase Chain Reaction (PCR) method. The kit contains: PCR mix, PCR buffer, Taq-AT-polymerase, Mineral oil
3	PCR Kit/PCR-Diagnostics	Folate Metabolism REAL-TIME PCR Genotyping Kit	All others	R1-H908-N3/4EU	The Folate Metabolism REAL-TIME PCR Genotyping Kit is designed to detect and discriminate four genetic polymorphisms associated with folic acid metabolism disturbances (OMIM #236250; #250940; #236270) with an aid of Polymerase Chain Reaction (PCR) method. The kit contains: PCR mix, PCR buffer, Taq-AT-polymerase, Mineral oil
4	PCR Kit/PCR-Diagnostics	Warfarin Pharmacogenetics REAL-TIME PCR Genotyping Kit	All others	R1-H904-N3/4EU	The Warfarin Pharmacogenetics REAL-TIME PCR Genotyping Kit is designed to detect and discriminate nine genetic polymorphisms associated with warfarin anticoagulant resistance (OMIM #122700) with an aid of Polymerase Chain Reaction (PCR) method. The kit contains: PCR mix, PCR buffer, Taq-AT-polymerase, Mineral oil
5	PCR Kit/PCR-Diagnostics	BRCA mutations REAL-TIME PCR Genotyping Kit	All others	R1-H927-N3/4EU	The BRCA mutations REAL-TIME PCR Genotyping Kit is designed to detect and discriminate eight genetic polymorphisms associated with breast cancer (OMIM #604370; #612555) with an aid of Polymerase Chain Reaction (PCR) method. The kit contains: PCR mix, PCR buffer, Taq-AT-polymerase, Mineral oil
6	PCR	IL28B REAL-TIME PCR	All	R1-H930-	The IL28B REAL-TIME PCR

	Kit/PCR-Diagnostics	**Genotyping Kit**	**others**	**N3/4EU**	**Genotyping Kit is designed to detect and discriminate two genetic polymorphisms associated with susceptibility to hepatitis C virus (OMIM #609532) with an aid of Polymerase Chain Reaction (PCR) method. The kit contains: PCR mix, PCR buffer, Taq-AT-polymerase, Mineral oil**
7	**PCR Kit/PCR-Diagnostics**	**Lactose Intolerance REAL-TIME PCR Genotyping Kit**	**All others**	**R1-H941-N3/4EU**	**The Lactose Intolerance REAL-TIME PCR Genotyping Kit is designed to detect and discriminate one genetic polymorphism associated with adult type hypolactasia (OMIM #223100) with an aid of Polymerase Chain Reaction (PCR) method. The kit contains: PCR mix, PCR buffer, Taq-AT-polymerase, Mineral oil**
8	**PCR Kit/PCR-Diagnostics**	**Hemochromatosis REAL-TIME PCR Genotyping Kit**	**All others**	**R1-H939-N3/4EU**	**The Hemochromatosis REAL-TIME PCR Genotyping Kit is designed to detect and discriminate three genetic polymorphisms associated with hereditary hemochromatosis (OMIM #235200) with an aid of Polymerase Chain Reaction (PCR) method. The kit contains: PCR mix, PCR buffer, Taq-AT-polymerase, Mineral oil**

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

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Mr. Vladimir Dmitrovskiy
Position: General Director
Signature:
Date : 29 July 2019
Stamp

European Authorized Representative:
Registered Address:
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Phone: 32.2.732.59.54
Fax: 32.2.732.60.03
E-mail: mail@obelis.net
Representative: Mr. Gideon ELKAYAM (CEO)

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

"DNA-Technology, Research&Production", LLC
Address:142281, Moscow region, Protvino, Zheleznodorozhnaya street, 20
Country: Russia

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

- *Please refer to the attached Annex to Declaration of Conformity*

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:
- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

- ISO 9001: 2015
- ISO 13485:2016

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Annex to the Declaration of Conformity

DEVICE	CATALOGUE REFERENCE NUMBER	NUMBER OF TESTS	COMPONENTS	SHORT DESCRIPTION AND INTENDED USE
EBV REAL-TIME PCR Detection Kit	R1-P205-S3/9EU (0.2 ml strips)	**96**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Positive control	**The EBV REAL-TIME PCR Detection Kit and EBV FLASH PCR Detection Kit are intended for research and diagnostic applications. The EBV REAL-TIME PCR Detection Kit and EBV FLASH PCR Detection Kit are an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The EBV REAL-TIME PCR Detection Kit and EBV FLASH PCR Detection Kit are designed to detect Epstein Barr virus nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
	R1-P205-23/9EU (0.2 ml tubes)	**96**		
EBV FLASH PCR Detection Kit	F1-P205-21/1EU (0.2 ml tubes)	**100**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Background buffer ▪ Positive control	
	F1-P205-51/1EU (0.5 ml tubes)	**100**		
EBV REAL-TIME PCR Detection Kit (Rotor-Gene)	R1-P205-24/9EU (0.2 ml tubes)	**96**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Positive control	
HSV 1, 2 REAL-TIME PCR Detection Kit	R1-P201-S3/9EU (0.2 ml strips)	**96**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Positive control	**The HSV 1, 2 REAL-TIME PCR Detection Kit and HSV 1, 2 FLASH PCR Detection Kit are intended for research and diagnostic applications. The HSV 1, 2 REAL-TIME PCR Detection Kit and HSV 1, 2 FLASH PCR Detection Kit are an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The HSV 1, 2 REAL-TIME PCR Detection Kit and HSV 1, 2 FLASH PCR Detection Kit are designed to detect Herpes symplex virus 1, 2 nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
	R1-P201-23/9EU (0.2 ml tubes)	**96**		
HSV 1, 2 FLASH PCR Detection Kit	F1-P201-21/1EU (0.2 ml tubes)	**100**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Background buffer ▪ Positive control	
	F1-P201-51/1EU (0.5 ml tubes)	**100**		
HSV 1, 2 REAL-TIME PCR Detection Kit (Rotor-Gene)	R1-P201-24/9EU (0.2 ml tubes)	**96**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Positive control	
HPV-QUANT-4® quantitative Real-Time PCR Detection Kit	R1-P315-S3/4EU (0.2 ml strips)	**48**	▪ Paraffin sealed PCR-mix for HPV 6,11 amplification ▪ Paraffin sealed PCR-mix for	**The HPV-QUANT-4 quantitative PCR Detection Kit is intended for research and diagnostic applications. The HPV-QUANT-4 quantitative PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The HPV-QUANT-4 quantitative PCR**

DEVICE	CATALOGUE REFERENCE NUMBER	NUMBER OF TESTS	COMPONENTS	SHORT DESCRIPTION AND INTENDED USE
			HPV 16,18 amplification ▪ Paraffin sealed PCR-mix for SIC amplification ▪ Taq-polymerase solution ▪ Mineral oil ▪ Positive control	**Detection Kit is intended for the specific identification and quantification of low-risk (HPV 6,11) and high-risk (HPV 16,18) in regard to their oncogenic properties human papillomaviruses nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
HPV-QUANT-21® quantitative Real-Time PCR Detection Kit	R1-P317-S3/5EU (0.2 ml strips)	**24**	▪ Paraffin sealed PCR-mix ▪ MAX Taq-polymerase solution ▪ Mineral oil ▪ Positive control	**The HPV-QUANT-21® quantitative PCR Detection Kit is intended for research and diagnostic applications. The HPV-QUANT-21® quantitative PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The HPV-QUANT-21® quantitative PCR Detection Kit is intended for the specific identification and quantification of low-risk (HPV 6, 11, 44) and high-risk (HPV 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82) in regard to their oncogenic properties human papillomaviruses nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
Legionella pneumophila Real-Time PCR Detection Kit	R1-P403-S3/4EU (0.2 ml strips)	**48**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Positive control	**The Legionella pneumophila PCR Detection Kit is intended for research and diagnostic applications. The Legionella pneumophila PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Legionella pneumophila PCR Detection Kit is designed to detect Legionella pneumophila nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
	R1-P403-23/4EU (0.2 ml tubes)	**48**		
Legionella pneumophila FLASH PCR Detection Kit	F1-P403-21/2EU (0.2 ml tubes)	**50**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Background buffer ▪ Positive control	
	F1-P403-51/2EU (0.5 ml tubes)	**50**		
Legionella pneumophila Real-Time PCR Detection Kit (Rotor-Gene)	R1-P403-24/4EU (0.2 ml tubes)	**48**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Positive control	

DEVICE	CATALOGUE REFERENCE NUMBER	NUMBER OF TESTS	COMPONENTS	SHORT DESCRIPTION AND INTENDED USE
M. tuberculosis – M. bovis FLASH PCR Detection Kit	F1-P404-51/2EU (0.5 ml tubes)	**50**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Background buffer ▪ Positive control	**The M. tuberculosis – M. bovis REAL-TIME PCR Detection Kit and M. tuberculosis – M. bovis FLASH PCR Detection Kit are intended for research and diagnostic applications. The Kits are an in vitro Nucleic Acid Test (NAT) – based pathogen detection products. The Kits are designed to detect Mycobacterium tuberculosis and Mycobacterium bovis nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
	F1-P404-21/2EU (0.2 ml tubes)	**50**		
M. tuberculosis – M. bovis REAL-TIME PCR Detection Kit	R1-P404-23/4EU (0.2 ml tubes)	**48**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Positive control	
	R1-P404-S3/4EU (0.2 ml strips)	**48**		
M. tuberculosis – M. bovis REAL-TIME PCR Detection Kit (Rotor-Gene)	R1-P404-24/4EU (0.2 ml tubes)	**48**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Positive control	
VZV REAL-TIME PCR Detection Kit	R1-P206-S3/4EU (0.2 ml strips)	**48**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Positive control	**The VZV REAL-TIME PCR Detection Kit and VZV FLASH PCR Detection Kit are intended for research and diagnostic applications. The Kits are an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Kits are designed to detect Varicella zoster virus nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
	R1-P206-23/4EU (0.2 ml tubes)	**48**		
VZV FLASH PCR Detection Kit	F1-P206-21/2EU (0.2 ml tubes)	**50**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Background buffer ▪ Positive control	
	F1-P206-51/2EU (0.5 ml tubes)	**50**		
VZV REAL-TIME PCR Detection Kit (Rotor-Gene)	R1-P206-24/4EU (0.2 ml tubes)	**48**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Positive control	
AZF Microdeletions REAL-TIME PCR Genotyping Kit	R1-H801-S3/5EU (0.2 ml strips)	**24**	▪ Paraffin sealed PCR-mix ▪ Taq-polymerase solution ▪ Mineral oil ▪ Positive control	**The AZF Microdeletions REAL-TIME PCR Genotyping Kit is intended for research and diagnostic applications. The AZF MicrodeletionsREAL-TIME PCR Genotyping Kit is in vitro Nucleic Acid Test (NAT) – based human genotyping product. The AZF MicrodeletionsREAL-TIME PCR Genotyping Kit is intended for**

DEVICE	CATALOGUE REFERENCE NUMBER	NUMBER OF TESTS	COMPONENTS	SHORT DESCRIPTION AND INTENDED USE
				detection of AZF locus deletions which are the common cause of male infertility defined by loss of spermatozoids motion ability (azoospermia) with an aid of Polymerase Chain Reaction (PCR) method.
Influenza A virus (subtype H1N1) PCR Detection Kit	R3-P408-23/4EU (0.2 ml tubes)	**48**	▪ Paraffin sealed PCR-mix ▪ Positive control ▪ "RT-RANDOM" package	**The Influenza A virus (subtype H1N1) PCR Detection Kit is intended for research and diagnostic applications. The Influenza A virus (subtype H1N1) PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Influenza A virus (subtype H1N1) PCR Detection Kit is designed to detect Influenza A virus (subtype H1N1) nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
	R3-P408-S3/4EU (0.2 ml strips)	**48**		
HPV-QUANT-15® quantitative PCR Detection Kit	R1-P316-S3/4EU (0.2 ml strips)	**48**	▪ Paraffin sealed PCR-mix ▪ MAX Taq-polymerase solution ▪ Mineral oil ▪ Positive control	**The HPV-QUANT-15 quantitative PCR Detection Kit is intended for research and diagnostic applications. The HPV-QUANT-15 quantitative PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The HPV-QUANT-15® quantitative PCR Detection Kit is intended for the the specific identification and quantification of low- and high-risk (in regard to oncogenic properties) human papillomaviruses including: low-risk HPV types 6 and 11 without differentiation high-risk HPV types 16, 31, 33, 35, 52, 58 without differentiation HPV types 18, 39, 45, 59 without differentiation HPV type 56 HPV type 51 HPV type 68 in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
Influenza A virus Real-Time PCR Detection Kit	R3-P409-23/4EU (0.2 ml tubes)	**48**	▪ Paraffin sealed PCR-mix ▪ Positive control ▪ "RT-RANDOM" package	**The Influenza A virus PCR Detection Kit is intended for research and diagnostic applications. The Influenza A virus PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Influenza A virus PCR Detection Kit is designed to detect Influenza A virus nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
	R3-P409-S3/4EU (0.2 ml strips)	**48**		

DEVICE	CATALOGUE REFERENCE NUMBER	NUMBER OF TESTS	COMPONENTS	SHORT DESCRIPTION AND INTENDED USE
Influenza B virus Real-Time PCR Detection Kit	R3-P410-23/4EU (0.2 ml tubes)	**48**	▪ Paraffin sealed PCR-mix ▪ Positive control ▪ "RT-RANDOM" package	**The Influenza B virus PCR Detection Kit is intended for research and diagnostic applications. The Influenza B virus PCR Detection Kit is an in vitro Nucleic Acid Test (NAT) – based pathogen detection product. The Influenza B virus PCR Detection Kit is designed to detect Influenza B virus nucleic acids in human biological samples with an aid of Polymerase Chain Reaction (PCR) method.**
	R3-P410-S3/4EU (0.2 ml strips)	**48**		

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Mr. Vladimir Dmitrovskiy
Position: General Director

Signature: _____

Date: 29 July 2019

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Declaration of Conformity

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Country: Russia

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

#	Catalogue reference number	Commercial Name	Short description and intended use	Class
1.	P-910-1/1EU	STOR-M transport medium	The STOR-M transport medium is intended for transport and storage of human biological samples (scrapes/swabs of epithelial cells from urogenital tract, oropharynx, nasopharynx, rectum, skin, conjunctiva of the eye), including those containing an impurity of mucus, followed by nucleic acids analysis (human and microbial DNA, viral RNA) by polymerase chain reaction method.	neither A or B according II IVD 98/79/EC
2.	P-001/1EU P-021/4EU	PREP-RAPID DNA Extraction Kits	The PREP-RAPID DNA Extraction Kit is intended for DNA extraction from biological materials (saliva, urine, prostatic fluid, cerebrospinal fluid, epithelial cells scrapes from posterior pharyngeal wall, urethra, cervical canal, posterior vaginal vault etc.) for further analysis by polymerase chain reaction (PCR). The PREP-RAPID Genetics DNA Extraction Kit is intended for DNA extraction from whole peripheral blood for further DNA genetic testing by PCR.	neither A or B according II IVD 98/79/EC
3.	P-002/1EU P-002/2EU	PREP-NA DNA/RNA Extraction Kits	The PREP-NA and PREP-NA PLUS DNA/RNA Extraction Kits are intended for DNA/RNA extraction from biological materials for further analysis with reverse transcription (RNA) and/or polymerase chain reaction (DNA). In the PREP-NA PLUS DNA/RNA Extraction Kit the total volume of purified DNA/RNA is larger comparing to standard PREP-NA DNA/RNA Extraction Kit (50 µL) for more PCR tests.	neither A or B according II IVD 98/79/EC
4.	P-007-N/1EU	PREP-NA-S DNA/RNA Extraction Kit	The ***PREP-NA-S* DNA/RNA Extraction Kit** is intended for fast NA extraction from biological materials for further analysis by RT-PCR (PCR with Reverse Transcription)/PCR (polymerase chain reaction). The ***PREP-NA-S* DNA/RNA Extraction Kit** is designed to extract NA from biological materials: nasopharyngeal, oropharyngeal swabs.	neither A or B according II IVD 98/79/EC

5.	P-003/1EU, P-003/2EU, P-023/4EU	PREP-GS DNA Extraction Kits	The PREP-GS and PREP-GS PLUS DNA Extraction Kits are intended for DNA extraction from biological materials for further analysis by polymerase chain reaction (PCR). In the PREP-GS PLUS DNA Extraction Kit the total volume of purified DNA is larger comparing to standard PREP-GS DNA Extraction Kit for more PCR tests. The PREP-GS Genetics DNA Extraction Kit is intended for DNA extraction from whole peripheral blood for further DNA genetic testing by PCR.	neither A or B according II IVD 98/79/EC
6.	R1-P023-S3/5EU	MycosoScreen REAL-TIME PCR Detection Kit	The ***MycosoScreen*** **REAL-TIME PCR Detection Kit** is intended for detection and typing of fungal infectious agents from genus Candida, Malassezia, Saccharomyces and Debaryomyces: Meyerozyma guilliermondii (C. guilliermondii), Candida albicans, Pichia kudriavzevii (C.krusei), Saccharomyces cerevisiae, Candida auris, Candida tropicalis, Clavispora lusitaniae (C.lusitaniae), Debaryomyces hansenii (C.famata), Candida dubliniensis, Candida glabrata, Candida parapsilosis, Malassezia spp., Kluyveromyces marxianus (C.kefyr), Malassezia furfur. Samples are human biological material (blood, phlegm, urine, swabs/scrapes from respiratory tract, gastrointestinal and urogenital tracts, faeces, bioptates), catheter and endotracheal tube washings, and fungal cultures.	neither A or B according II IVD 98/79/EC
7.	R1-H004-23/4EU, R1-H004-S3/4EU, R1-H004-N3/4EU	HLA-B27 REAL-TIME PCR Genotyping Kit	The HLA-B27 REAL-TIME PCR Genotyping Kit is intended for rapid group-specific detection of HLA-B27 alleles (major histocompatibility complex, class I, B) by Real-Time PCR method. Samples are human biological materials: peripheral blood. These alleles are generally recognized as a genetic marker of multiple disease conditions e.g. rheumatoid arthritis and ankylosing spondylitis (Bekhterev's disease). Indications for the use: - the presence of clinical symptoms of spondyloarthropathies: inflammatory back pain, asymmetric peripheral oligoarthritis, mainly of the lower extremities, enteritis and/or tendosynovitis; - as an additional laboratory indicator for predicting the severity of spondyloarthropathies	neither A or B according II IVD 98/79/EC
8.	R1-P501-S3/9EU, R1-P501-23/9EU R1-P501-UA/9EU	Helicobacter pylori REAL-TIME PCR Detection Kit	The Helicobacter pylori REAL-TIME PCR Detection Kit is designed to detect Helicobacter pilory DNA in human biological samples with an aid of Polymerase Chain Reaction (PCR) method. Samples are human biological materials: bioptates, faeces.	neither A or B according II IVD 98/79/EC
9.	R1-P028-S3/6EU	BacScreen OM REAL-TIME PCR Detection Kit	The ***BacScreen OM*** **REAL-TIME PCR Detection Kit** is designed for DNA analysis of opportunistic bacteria from classes Bacilli, Betaproteobacteria and Gammaproteobacteria that cause nosocomial and community-acquired infections with an aid of Polymerase Chain Reaction (PCR) method. Samples are human biological materials (phlegm, urine, swabs/scrapes of epithelial cells from respiratory tract, gastrointestinal tract and urogenital tract, feaces, aspirates, exudates) and bacterial cultures.	neither A or B according II IVD 98/79/EC
10.	R1-P026-S3/5EU, R1-P027-S3/4EU, R1-P027-23/4EU	BacResista GLA REAL-TIME PCR Detection Kits	The BacResista GLA and BacResista Gla Van/Mec REAL-TIME PCR Detection Kits are designed for DNA analysis of bacteria resistant to glycopeptide (G) and beta-lactam (L) antibiotics (A) in DNA material obtained from biological samples and bacterial cultures with an aid of Polymerase Chain Reaction (PCR) method. Samples are human biological materials (phlegm, urine, swabs of epithelial cells from respiratory tract, gastrointestinal tract and urogenital tract, feaces, aspirates, exudates) and bacterial cultures. Indications for the use: the need to study a possible antibiotic resistance in bacteria that caused infectious disease.	neither A or B according II IVD 98/79/EC

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

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- ISO 9001:2015
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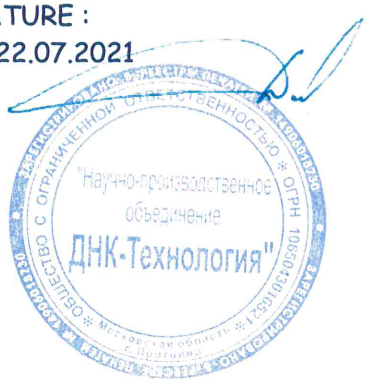

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Declaration of Conformity

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We,

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#	Catalogue reference number	Commercial Name	Short description and intended use	Class
1.	R3-P439-S3/5EU	AVRI Panel Multiplex REAL-TIME PCR Detection Kit	The AVRI Panel Multiplex REAL-TIME PCR Detection Kit is designed to detection of the most common causative agents of acute viral respiratory infections by Real-Time PCR method. Samples are human biological materials: nasopharyngeal swabs, oropharyngeal swabs, bronchoalveolar lavage, endotracheal aspirate, nasopharyngeal aspirate, phlegm.	neither A or B according II IVD 98/79/EC
2.	R3-P446-S3/9EU	SARS-CoV-2 Lite REAL-TIME PCR Detection Kit	The SARS-CoV-2 Lite REAL-TIME PCR Detection Kit is designed to detect Coronavirus SARS-CoV-2 in human biological samples (nasopharyngeal smears, oropharyngeal smears) with an aid Reverse Transcription (RT) and of Polymerase Chain Reaction (PCR) methods.	neither A or B according II IVD 98/79/EC
3.	R1-P815-S3/6EU R1-P815-XA/5EU	ENTEROFLOR Kiddy REAL-TIME PCR Detection Kit	The ENTEROFLOR Kiddy REAL-TIME PCR Detection Kit is designed for detection of colon associated bacteria DNA (Firmicutes, Proteobacteria, Bacteroidetes, Actinobacteria, Fusobacteria, Verrucomicrobia, Euryarchaeota filums), including Candida fungi, as well as gene of methicillin-resistance Staphylococcus spp. (mecA), Cl.difficile with enterotoxins A and B (tcdA, tcdB), Str.agalactiae with invasiveness marker gene (srr2) by real-time PCR in DNA preparations obtained from children's faeces sample.	neither A or B according II IVD 98/79/EC
4.	P-016-N/2EU P-016-1/2EU P-015-N/2EU	PREP-OPTIMA DNA Extraction Kit	The PREP-OPTIMA DNA Extraction Kit is intended for human, bacterial, viral, and fungal DNA extraction from human biological material (blood; buccal epithelium; smears/scrapings from respiratory, gastrointestinal, and urogenital tracts; urine; faeces; bioptates; amniotic liquid; ejaculate; cerebrospinal fluid; breast milk), as well as for DNA extraction from microbial cultures (bacterial, fungal) received from this biological material for further PCR analysis.	neither A or B according II IVD 98/79/EC

5.	R1-H958-N3/4EU R1-H959-N3/4EU	Hemostasis F2, F5 mutations REAL-TIME PCR Genotyping Kit	The Hemostasis F2, F5 mutations REAL-TIME PCR Genotyping Kit is intended for detection and allelic discrimination of the genetic polymorphisms associated with risk of health complications provided by hormonal contraception use or in case of passing by hormonal replacement therapy. Samples are peripheral blood..	neither A or B according II IVD 98/79/EC
6.	R1-H806-S3/4EU R1-H806-UA/4EU R1-H807-S3/4EU R1-H807-UA/4EU	EGFR mutations REAL-TIME PCR Genotyping Kit	The EGFR mutations REAL-TIME PCR Genotyping Kit is intended for the detection of somatic mutations in the EGFR gene (deletions and insertions in the 19th exon, insertions in the 20th exon, mutations L858R, T790M, L861Q, S768I and G719X) by real-time PCR in human genomic DNA extracted from formaldehyde-fixed paraffin-embeded (FFPE) non-small-cell lung cancer samples in order to choose the patients for target therapy with tyrosinkinase inhibitors. (C.famata), Candida dubliniensis, Candida glabrata, Candida parapsilosis, Malassezia spp., Kluyveromyces marxianus (C.kefyr), Malassezia furfur. Samples are human biological material (blood, phlegm, urine, swabs/scrapes from respiratory tract, gastrointestinal and urogenital tracts, faeces, bioptates), catheter and endotracheal tube washings, and fungal cultures.	neither A or B according II IVD 98/79/EC
7.	P-028-N/2EU P-030-N/2EU	PREP-PK Kit for sample pretreatment while processing of nucleic acids isolation	The PREP-PK kit is intended for the removal of inhibiting effects causing by fixation and proteolysis by proteinase K in human biomaterial (formaldehyde-fixed paraffinin-embadded (FFPE) tissues, native tissues, cervical swabs taken in fixing transport medium for liquid-based cytology) before nucleic acid extraction for molecular-genetic analysis by PCR method.	neither A or B according II IVD 98/79/EC
8.	R1-P012-S3/4EU R1-P012-23/4EU R1-P012-UA/9EU	Streptococcus agalactiae REAL-TIME PCR Detection Kit	The Streptococcus agalactiae REAL-TIME PCR Detection Kit is intended for Streptococcus agalactiae (group B streptococcus) DNA detection in human biological samples (blood, phlegm, urine, scrapes from respiratory tract, urogenital and gastrointestinal tracts, faeces or meconium, bioptates, cerebrospinal fluid), washings from catheters and endotracheal tubes and bacterial cultures by polymerase chain reaction with detection in real-time.	neither A or B according II IVD 98/79/EC

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

- ISO 9001:2015
- ISO 13485:2016

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Date : 10.03.2022
Stamp

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Representative: Mr. Gideon ELKAYAM (CEO)

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

Name: "DNA-Technology Research&Production", LLC
Address: 142281, Moscow region, Protvino, Zheleznodorozhnaya street 20
Country: Russia

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

#	Catalogue reference number	Commercial Name	Short description and intended use	Class
1.	R1-P029-S3/6EU R1-P029-XA/5EU	BacScreen Pneumo REAL-TIME PCR Detection Kit	BacScreen Pneumo REAL-TIME PCR Detection Kit is designed for DNA analysis of bacteria from classes Bacilli, Betaproteobacteria, Chlamydia, Gammaproteobacteria and Mollicutes causing respiratory nosocomial and community-acquired infections and their complications (sepsis), in human biological material (sputum, aspirates, bioptates, exudates, smears/scrapes, washings from respiratory tract), bacterial cultures from this biomaterial and hemocultures, by real-time polymerase chain reaction	neither A or B according II IVD 98/79/EC
2.	R1-H803-S3/9EU R1-H803-23/9EU R1-H803-UA/9EU	Fetal Gender REAL-TIME PCR Detection Kit	Fetal Gender REAL-TIME PCR Detection Kit is intended for the detection of multi-copy fragment of Y chromosome in samples of cell-free fetal DNA extracted from the blood of pregnant women by Real-Time PCR method.	neither A or B according II IVD 98/79/EC
3.	R1-H802-S3/9EU R1-H802-23/9EU	Fetal RHD Genotyping REAL-TIME PCR Kit	Fetal RHD Genotyping REAL-TIME PCR Kit is designed to detect cell-free fetal DNA of RHD gene in the blood of Rhd-negative pregnant women with an aid of Polymerase Chain Reaction (PCR) method in order to predict the risk of Rh-disease and hemolytic disease of the fetus and newborn	neither A or B according II IVD 98/79/EC
4.	R1-H810-S3/9EU R1-H810-23/9EU	NeoScreen SMA/TREC/KREC REAL-TIME PCR Detection Kit	NeoScreen SMA/TREC/KREC REAL-TIME PCR Detection Kit is designed to detect homozygous deletion of exon 7 of the SMN1 gene and assess the content of T cell receptor excision circles (TREC) and kappadeleting recombination excision circle (KREC) in newborn biological material (whole blood, dried blood spots) for screening for spinal muscular atrophy and primary immunodeficiencies by real-time PCR	neither A or B according II IVD 98/79/EC

5.	P-029-N/2EU	PREP-CITO DBS DNA Extraction Kit	The PREP-CITO DBS DNA Extraction Kit is intended for human genomic DNA extraction from dried blood spots (DBS) for further analysis with polymerase chain reaction (PCR)	neither A or B according II IVD 98/79/EC
6.	P-119-A/9EU P-119-N/9EU P-119-P/9EU P-120-P/9EU P-121-P/9EU	PREP-MB DWP DNA/RNA Extraction Kit	PREP-MB DWP DNA/RNA Extraction Kit is designed to extract NA from biological materials: nasopharyngeal, oropharyngeal swabs	neither A or B according II IVD 98/79/EC
7.	P-103-N/4EU P-103-A/8EU	PREP-MB MAX DNA Extraction Kit	PREP-MB MAX DNA Extraction Kit is intended for human, bacterial, viral, and fungal DNAextraction from human biological material (whole peripheral blood; smears/scrapings from urogenitaltract and rectum; urine; ejaculate; milk; faeces) for further PCR analysis.	neither A or B according II IVD 98/79/EC
8.	P-027/2EU	PREP-NA-FET DNA Extraction Kit	The PREP-NA-FET DNA Extraction Kit is intended for fetal DNA purification from peripheral blood of pregnant women.	neither A or B according II IVD 98/79/EC
9.	P-901-1/1EU P-901-R/1EU P-901-N/1EU	STOR-F transport medium	The STOR-F transport medium is intended for transport and storage of human biological samples (scrapes/smears of epithelial cells from urogenital tract, oropharynx, nasopharynx, rectum, skin, conjunctiva of the eye) followed by nucleic acids analysis (human DNA, DNA of microorganisms, RNA of viruses) by polymerase chain reaction method	neither A or B according II IVD 98/79/EC

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

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- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
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Our current Quality System is formatted to international standards:

- ISO 9001:2015
- ISO 13485:2016

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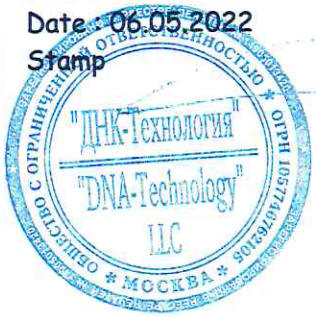
Date: 06.05.2022
Stamp



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