Obelis GROUP

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CERTIFICATE OF
IVDR NOTIFICATION

Reference No.: GDS 0319-2022 **Date:** 08/04/2022

Order No.: EU MM 0149-2022

This is to certify that, according to the Regulation (EU) 2017/746, we, here at Obelis s.a. performed all notification duties and responsibilities as the European Authorized Representative (EC REP) of:

Name:

Autobio Labtec Instruments Co. Ltd.

Address: No. 199, 15th Ave,
National Eco & Tech Zone, 450016,
Zhengzhou, China

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED REGULATION.

The manufacturer declares that the Class A devices comply with the Regulation including all general safety and performance requirements.

The Manufacturer has provided Obelis s.a. (EC REP) with all the appropriate declarations as per the Regulation (EU) 2017/746 article 48 requirements, including the EC Declaration of Conformity (according to annex IV) confirming that their Class A in vitro diagnostic medical devices, as stipulated here below, are fulfilling the applicable requirements of the Regulation (EU) 2017/746.

The notification of the following in vitro diagnostic medical devices has been completed by Obelis s.a. (EC REP) in compliance with the Regulation (EU) 2017/746 on the 25/03/2022

CLASS OF IVD DEVICES: Please See Annex A - List of Devices (4 Pages, 16 Devices)

As of the 26/03/2022 , and provided that the Manufacturer will continue complying with the hereabove mentioned requirements*, he therefore:

- Is required to affix the CE marking on these devices;
- May place these devices in the European Union and EEA territory.

Obelis -1988-

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Mr. G. Elkayam CEO
Obelis sa

Digitally signed by Jighili Tatiana
Date: 2022.07.29 12:09:45 EEST
Reason: MoldSign Signature
Location: Moldova

EA AR

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 or removal of the products from EAR Mandate

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Annex A - List of Devices

Regulation (EU) 2017/746 on in vitro diagnostic medical devices

#	Catalogue reference number	Commercial Name &Model	Short description and intended use	Device already on the EU market? (y/n)	Legacy Device (y/n)	GMDN Code	GIVD Code	BASIC UDI - DI	Risk class	Classific. Rule
1	07021	Automatic Luminescence Immunoassay Analyzer "AutoLumo A2000 Plus"	AutoLumo A2000 Plus is strictly intended for professional In-vitro Diagnostic use. It is clinically used for qualitative and quantitative assay of analyte derived from human sample such as serum, plasma or urine, including tumor-associated antigens, liver disease, hormones, infectious diseases, immune function, autoantibodies, proteins and peptides, cardiac disease, vitamins, amino acids and blood concentrations, allergens.	N	Y	56701	21.02.10.01	697304909Model 50UD	Class A	Rule 5
2	07031	Automatic Luminescence Immunoassay Analyzer "AutoLumo A1000"	AutoLumo A1000 is strictly intended for professional In-vitro diagnostic use. It is a fully automated instrument which is used to analyze various kinds of immunoassay items derived from human body fluid samples.	N	Y	56701	21.02.10.01	697304909Model 52UH	Class A	Rule 5
3	01011	Microplate Luminometer "LUMO"	LUMO is strictly used for professional in vitro diagnosis. It is a semi-automatic equipment for quantitative testing of body fluids, which is used for auxiliary diagnosis of various biological trace substances in human body. When using this product, clinical diagnosis can not be based on a single measurement result, it can only be performed by the doctor after evaluating all clinical and laboratory tests.	N	Y	56679	21.02.10.01	697304909Model 54UM	Class A	Rule 5

4	03011	Microplate Photometer "PHOMO"	PHOMO is strictly used for professional in vitro diagnosis. It is a semi-automatic equipment for qualitative and semi quantitative testing of body fluids, which is used for auxiliary diagnosis of various biological trace substances in human body. When using this product, clinical diagnosis can not be based on a single measurement result, it can only be performed by the doctor after evaluating all clinical and laboratory tests.	N	Y	57864	21.02.10.01	697304909Model 55UP	Class A	Rule 5
5	02041	Microplate Washer "IWO"	IWO is strictly intended for professional In-vitro Diagnostic use. It is a semi-automatic equipment which is intended used for washing the sample plates in laboratory.	N	Y	57866	29.01.10.01	697304909Model 56UR	Class A	Rule 5
6	05011	Automated Blood Culture System "BC120"	BC120 is strictly intended for professional In-vitro Diagnostic use. It is an automated blood culture instrument which is clinically used in for detecting the microorganisms in human blood, sputum or other sterile body fluids under normal conditions through in vitro culture. It can realize the qualitative detection of analytes through continuous incubation, shock culture and automatic detection of aerobic culture bottles.	N	Y	56739	24.02.10.01	697304909Model 53UK	Class A	Rule 5
7	09011	Automated Nucleic Acid Purification and Real Time PCR System "AutoMolec 3000"	AutoMolec 3000 and AutoMolec 1600 is an in vitro molecular examination instrument integrating sample extraction and amplification analysis. It is based on the principle of polymerase chain reaction (PCR) and real-time fluorescence monitoring technology, automatically completes a series of operating steps from nucleic acid extraction and purification to amplification and examination. AutoMolec 3000 is intended for quantitative and qualitative examination of analytes in serum, plasma, whole blood, swab and sputum nucleic acid samples (DNA/RNA) from human body, such as pathogens and human gene polymorphism items, etc.	N	Y	48031	26.04.10.01	697304909Model 59UX	Class A	Rule 5
8	09031	Automated Nucleic Acid Purification and Real Time PCR System "AutoMolec 1600"		N	Y	48031	26.04.10.01	697304909Model 60UG	Class A	Rule 5

9	01121	Automated Sample Preparation System "AutoMimo 1200"	AutoMimo 1200 is intended for in vitro diagnostic use only. It is used for precision loading of reagents or human samples prior to the analysis phase of clinical laboratory analyzer	N	Y	61643	29.01.10.01	697304909Model 91UT	Class A	Rule 5
10	CMO0501	Sample Cup	Sample Cup is used on the Automatic Luminescence Immunoassay Analyzers. It is the sample container during the test procedure. This Sample Cup is for professional use only.	N	Y		21.02.30.01	697015090000049HP	Class A	Rule 5
11	CMO0601	Reaction Vessel	Reaction Vessel is used on the Automatic Luminescence Immunoassay Analyzers. It is the container where the immunoassay happens between sample and reagent during the measurement procedure. This Reaction Vessel(box) is for professional use only.	N	Y		21.02.30.01	697015090000049HM	Class A	Rule 5
12	CMO0701	Reaction Vessel（box)	Reaction Vessel(box) is used on the Automatic Luminescence Immunoassay Analyzers. It is the container where the immunoassay happens between sample and reagent during the measurement procedure. This Reaction Vessel(box) is for professional use only.	N	Y		21.02.30.01	697015090000089HS	Class A	Rule 5
13	PCRD0101	M3000-Tip Tray	M3000-Tip Tray is intended used to transfer the purified sample and add the amplification reagent into the PCR tube which will be amplified on the Automated Nucleic Acid Purification and Real Time PCR System during the test procedure. This M3000-Tip Tray is for professional use only.	N	Y	61298	26.01.30.01	697015090000084HG	Class A	Rule 5

14	PCRD0201	M1600-Tip Tray	M1600-Tip Tray is intended used to transfer the purified sample and add the amplification reagent into the PCR tube which will be amplified on the Automated Nucleic Acid Purification and Real Time PCR System during the test procedure. This M1600-Tip Tray is for professional use only.	N	Y	61298	26.01.30.01	697015090000085HJ	Class A	Rule 5
15	PCRD0301	M3000-PCR Tube	M3000-PCR Tube is intended used to carry the sample which will be amplified based on the PCR principle on the Automated Nucleic Acid Purification and Real Time PCR System during the test procedure. This M3000-PCR Tube is for professional use only.	N	Y	63801	26.01.30.01	697015090000086HL	Class A	Rule 5
16	PCRD0401	M1600-PCR Tube	M1600-PCR Tube is intended used to carry the sample which will be amplified based on the PCR principle on the Automated Nucleic Acid Purification and Real Time PCR System during the test procedure. This M1600-PCR Tube is for professional use only.	N	Y	63801	26.01.30.01	697015090000087HN	Class A	Rule 5

* 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

Obelis s.a.

Date: 08/04/2022

Stamp:

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