

CERTIFICATE OF IVDR NOTIFICATION

Reference No.: ED 0507-2024

Date: 06/09/2024

Order No.: EU AM 0187-2024

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:

Address:

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 device(s) has been completed by Obelis s.a. (EC REP) in compliance with the Regulation (EU) 2017/746 on the **05/09/2024**

CLASS OF IVD DEVICE(S): Please See Annex A - List of Devices (6 Pages, 9 Devices))

As of the **05/09/2024**, 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);
- May place this(ese) device(s) in the European Union and EEA territory.



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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.).
Obelis s.a. is ISO 9001 : 2015 and ISO 13485 : 2016 certified.



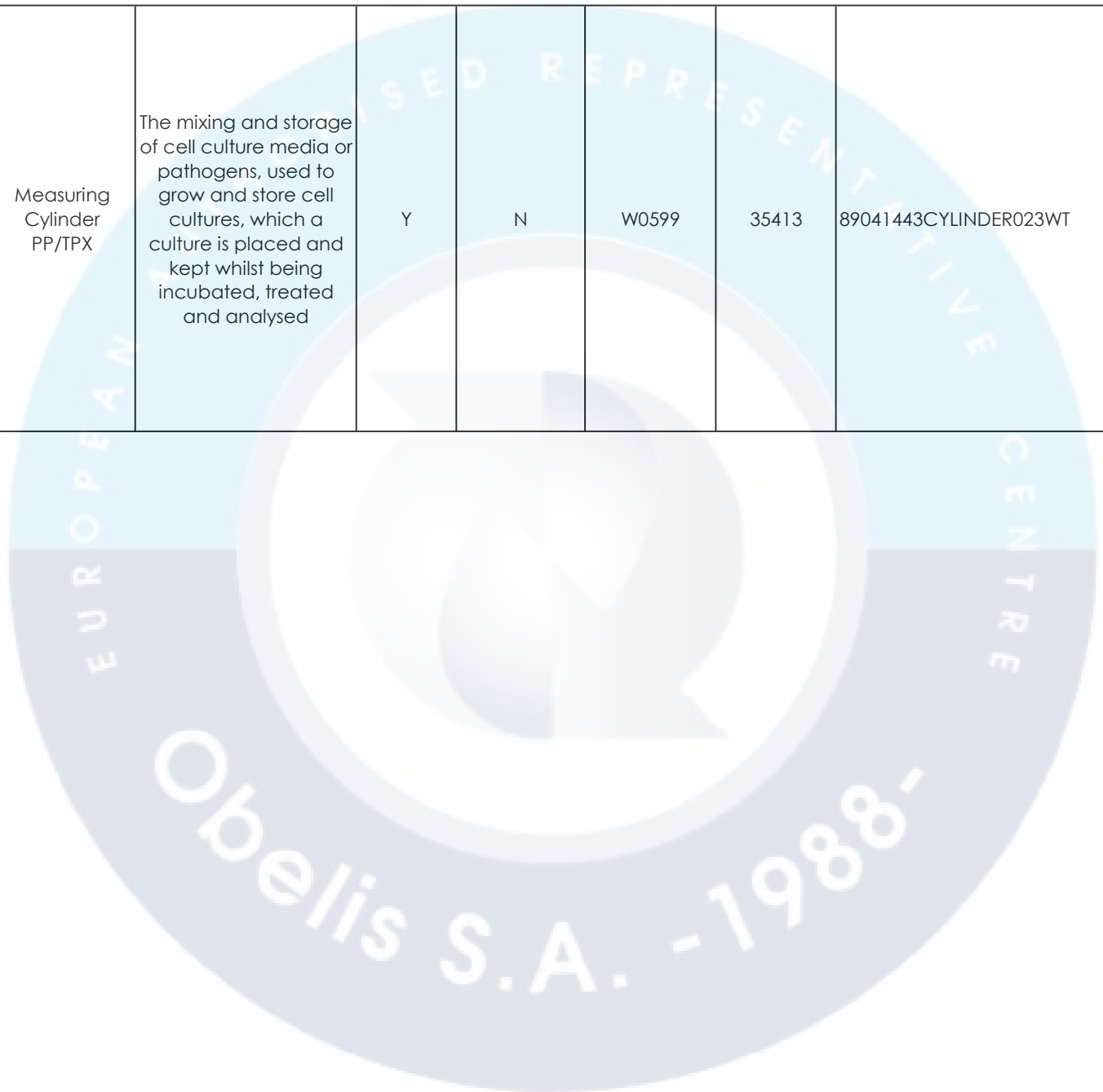
Annex A - List of Devices

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

#	Catalogue reference number	Commercial Name	Short description and intended use	Device already on the EU market? (y/n)	Legacy Device (y/n)	Nomenclature		BASIC UDI - DI	Risk class & Classification Rule	
						EMDN code	GMDN code		IVDD	IVDR
1	P10607,P10608,P10609,P10610,P10611,P10612 etc.	Serological Pipettes	To transfer the accurate amount of blood samples, serum, plasma, human tissue, wound samples for the detection of pathogen or genetically disease	Y	N	W050302010102	43375	89041443SEROLOGICAL015FM	All other, IVDS	Class A, Rule 5
2	P31207,P31201,P31209,P31205, etc.	Pasteur Pipettes	To transfer the accurate amount of blood samples, serum, plasma, human tissue, wound samples for the detection of pathogen or genetically disease	Y	N	W0503020199	43033	89041443PASTEUR016CV	All other, IVDS	Class A, Rule 5

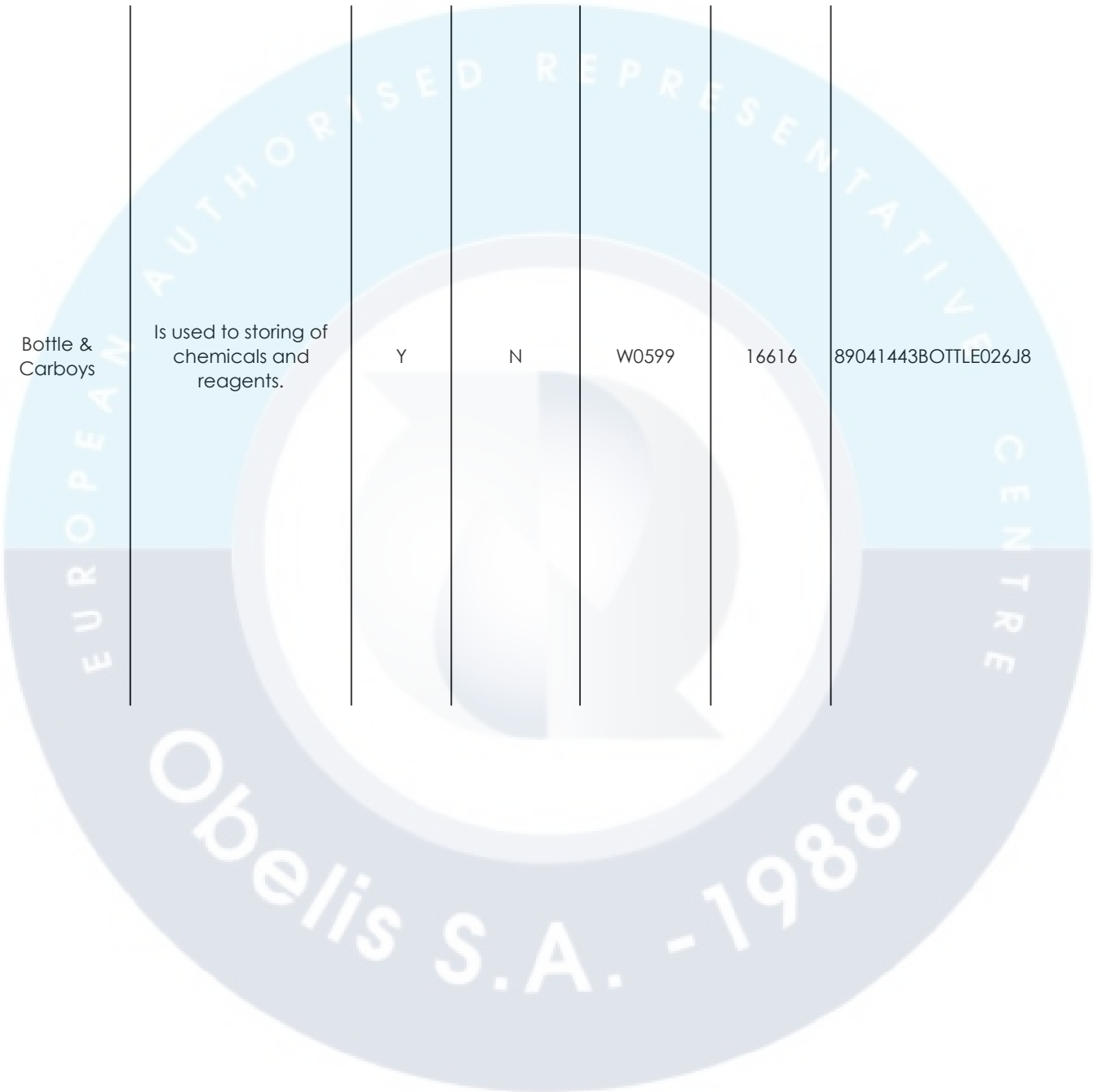
3	P11620,P11621,P11622,P50201, P50202,P50203,P50204, P50205, P50206,P50101,P50102, P50103, P50104,P50105,P50106, etc.	Conical / Volumetric Flask	To mixing & keeping the accurate amount of blood samples, serum, plasma, human tissue, wound samples for the detection of pathogen or genetically disease	Y	N	W0599	57952	89041443FLASK020SR	All other, IVDS	Class A, Rule 5
4	P21170,P21171,P21172,P21173,P21174,P21176,P21177, ,P21178,P21179 etc.	Media Bottles,PET & PETG	The mixing and storage of cell culture media or pathogens, used to grow and store cell cultures, which a culture is placed and kept whilst being incubated, treated and analysed	Y	N	W05030401	43398	89041443MEDIABOTTLE017J2	All other, IVDS	Class A, Rule 5
5	P50601,P50602,P50603,P50604,P50605,P50606,P50607, ,P50608,P50701,P50702,P50703,P50704, P50705,P50706,P50607,P50708,P50802,P50803,P50804, ,P50805,P50806,P50807,P50808,P50902, P50903,P50904,P50905,P50906,P50907,P50908,P50710 SET, etc.	Beaker PP/TPX	The mixing and storage of cell culture media or pathogens, used to grow and store cell cultures, which a culture is placed and kept whilst being incubated, treated and analysed	Y	N	W0599	35413	89041443BEAKER022WM	All other, IVDS	Class A, Rule 5

6	P50301,P50302,P50303,P50304,P50305,P50306,P50307,P50308,P50401,P50402,P50403,P50404,P50405,P50406,P50407,P50408,P50501,P50502,P50503,P50504,P50505,P50506,P50507,P50508, etc.	Measuring Cylinder PP/TPX	The mixing and storage of cell culture media or pathogens, used to grow and store cell cultures, which a culture is placed and kept whilst being incubated, treated and analysed	Y	N	W0599	35413	89041443CYLINDER023WT	All other, IVDS	Class A, Rule 5
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7	P20235,P20205,P20201,P20202,P20203,P20204,P20604,P20605,P20218,P20219,P20212,P20212,P20213,P20214,P20215,P20216,P20225,P20226,P20216,P20601,P20601A,P20602,P20602A,P20603,P20603A,20615,P20611,P20612,P20614,P20607,P20606,P20613,P10409,P10410,P20101,P20102,P20104,P20103,P20105,P20106,P20107,P11101,P11103,P20208,P20209,P20230,P20231,P20206,P20206A,P	Rackes & Boxes for IVD	Are used to hold, mix, or heat small quantities of solid or liquid chemicals especially for qualitative experiments and assays, subsequent in vitro diagnostic processing and or testing.	Y	N	W0599	62010	89041443RB025HD	All other, IVDS	Class A, Rule 5
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8	P11135,P11136,P11137,P11138,P11131,P11132,P11133,P11134,P11145,P11146,P11147,P11148,P11141,P11142,P11143,P11144,P11155,P11156,P11157,P11158,P11151,P11152,P11153,P11154,P11155A,P11156A,P11157A,P11158A,P11151A,P11152A,P11153A,P11154A,P11127,P11128,P11129,P11160,P11161,P11162,P11163,P11164,P11170,P11171,P11172,P11173,P11174,P11180,P11181,P11182,	Bottle & Carboys	Is used to storing of chemicals and reagents.	Y	N	W0599	16616	89041443BOTTLE026J8	All other, IVDS	Class A, Rule 5
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9	E11150,E11151,E11153,E11154,E11155,E11156,E11157,E11158,E1001,E10002,E10003,E10004,E10005,E10006,E10007,E10008,E10009,E10010,E11100,E11101,E11102,E11103,E11104,E11112,E11105,E11113,E11132,E11145,E11107,E11108,E11147,E11111,E11134,E11136,E11137,E11138,E11139,E11140,E11141,E11161,E11162,E11163,E11164,E11501,E11502,E11503,E11510,E11511,E11512,E11513	Laboratory Instruments	Subsequent in vitro diagnostic processing and or testing.	Y	N	W02079099	38522	89041443INSTRUMENT027UD	All other, IVDS	Class A, Rule 5
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Obelis s.a.

Date: 06/09/2024

Stamp:

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