

CERTIFICATE OF MHRA Medical Device Registration

Reference No.: UK CPCM 0007-2025

Date: 21/01/2025

Order No.: UK AM 0125-2024

This is to certify that, according to Medical Device Regulations 2002 (UK MDR 2002) as amended by Medical Device regulations (Amendment etc.) (EU Exit) Regulations 2020 (MDRs 2020), We, here at Obelis UK Ltd. performed all registration duties and responsibilities as the UK Responsible Person (UK RP) of:

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED STATUTORY INSTRUMENT.

The Manufacturer declares that the device(s) comply(ies) with the Medical Device Regulations 2002 (UK MDR 2002) as amended by (EU Exit) MDRs 2020 including all essential requirements.

The Manufacturer has provided Obelis UK Ltd with all the appropriate information as per UK MDR 2002 as amended by (EU Exit) MDRs 2020 Reg. 17, 30 & 41 requirements, including the Declaration of Conformity in accordance with Reg. 13, 27 & 40 confirming that their device(s), as stipulated here below, is/are fulfilling the applicable requirements of UK MDR 2002 as amended by (EU Exit) MDRs 2020.

Product Categories:see annex A (17 products, 4 pages)

The registration of the following medical device(s) has been completed by Obelis UK Ltd via the MHRA portal application number **2025012101404652** on the 21/01/2025 in compliance with UK MDR 2002 (SI 2002 No. 618) as amended by (EU Exit) MDRs 2020- Regulation 19 requirements.



OBELIS UK Ltd
Sandford Gate, East Point Business Park
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Mr. G. Elkayam CEO
Obelis UK LTD.

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Annex A - List of Devices

The Medical Devices Regulations 2002 as amended by Medical Device regulations (Amendment etc.) (EU Exit) Regulations 2020

#	Commercial Name	Model***	Ref. Number	Generic Device Term	Short description and intended use	GMDN	Class	UDI-DI
1	Loop, Spreader & Scraper, Sterile	P10977, P10978, P10979, P10980, P10985, P10986, P10987, P10988, P10981, P10982, P10989, P10990, P10991, P10992, P10995, P10996, P21040, P21041, etc.		Loop, Spreader & Scraper, Sterile	It is used for spreading, inoculating, harvesting, detection of pathogen/ species & antibiotic sensitivity of the pathogen & Microbiology.	64876	Class A, All Others/ General IVDs	89041443LOOP014RJ
2	Serological Pipettes, Sterile	P10601, P10602, P10603, P10604, P10605, P10606 etc.		Serological Pipettes, Sterile	To transfer the accurate amount of blood samples, serum, plasma, human tissue, wound samples for the detection of pathogen or genetically disease	64876	Class A, All Others/ General IVDs	89041443SEROLOGICAL015FM
3	Serological Pipettes	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	64876	Class A, All Others/ General IVDs	89041443SEROLOGICAL015FM
4	Pasteur Pipettes	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	64876	Class A, All Others/ General IVDs	89041443PASTEUR016CV
5	Pasteur Pipettes, Sterile	P31208, P31202, P31210, P31206, etc.		Pasteur Pipettes, Sterile	To transfer the accurate amount of blood samples, serum, plasma, human tissue, wound samples for the detection of pathogen or genetically disease	64876	Class A, All Others/ General IVDs	89041443PASTEUR016CV
6	Microcentrifuge Tube, Sterile	P10202ST, P10201ST, P10203ST, P10201S, P10202S, P10203S etc.		Microcentrifuge Tube, Sterile	Hematocrite Centrifuge, To centrifuge the small volume of blood samples, serum, plasma, human tissue, wound samples for the detection of pathogen or genetically disease	43761	Class A, All Others/ General IVDs	89041443MCT001FU
7	Media Bottles, PET & PETG, Sterile	P21180, P21181, P21182, P21183, P21184, P21186, P21187, P21188, P21189, P21192, P21193, P21194, P21195, P21196 etc..		Media Bottles, PET & PETG, Sterile	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	47775	Class A, All Others/ General IVDs	89041443MEDIABOTTLE017J2
8	Biofill Bottle Top Filtration System Sterile	P21101, P21102, P21103, P21104, P21105, P21106, P21107, P21108, P21109, P21090, P21091, P21092, P21093, P21094, P21095, P21096, P21097, P21098, etc.		Biofill Bottle Top Filtration System Sterile	used to filter, grow and store cell cultures, which a culture is placed and kept whilst being incubated, treated and analysed	43685	Class A, All Others/ General IVDs	89041443BIOFIL0186U
9	Erlenmeyer Flask Sterile	P21200, P21201, P21202, P21203, P21204, P21205, P21206, P21207, P21212, P21213, P21214, P21215, P21216, P21217, P21218, P21219, P21220, P21221, P21222, P21223, P21224, P21225, P21226, P21227, etc.		Erlenmeyer Flask Sterile	To mixing & keeping the accurate amount of blood samples, serum, plasma, human tissue, wound samples for the detection of pathogen or genetically disease	57952	Class A, All Others/ General IVDs	89041443ERLENMEYER0194X
10	Flask Conical & Volumetric, Sterile/Non-sterile	P11620, P11621, P11622, P50201, P50202, P50203, P50204, P50205, P50206, P50101, P50102, P50103, P50104, P50105, P50106, P50201S, P50202S, P50203S, P50204S, P50205S, P50206S, etc.		Flask Conical & Volumetric	To mixing & keeping the accurate amount of blood samples, serum, plasma, human tissue, wound samples for the detection of pathogen or genetically disease	57952	Class A, All Others/ General IVDs	89041443FLASK020SR
11	Roller Bottles Sterile	P21060, P21061, P21062, P21063, P21064, P21065, P21066, P21067, P21068, P21069, etc.		Roller Bottles Sterile	used to grow and store cell cultures, which a culture is placed and kept whilst being incubated, treated and analysed	47775	Class A, All Others/ General IVDs	89041443ROLLER021NC

12	Media Bottles,PET & PETG	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	47775	Class A, All Others/ General IVDs	89041443MED/ABOTTLE017J2
13	Beaker,Sterile/Non-sterile	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,P50710SET, 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, This is a reusable device, This is used for general plastic labware for mixing, transfer or storage of chemical or biological reagents. Can be used to hold liquid or solid samples or as a container for reactions. They are also used to collect filtrates from filtering operations as well as liquids from titrations. It is used for stirring the liquid	62011	Class A, All Others/ General IVDs	89041443BEAKER022WWM
14	Measuring Cylinder,Sterile/Non-sterile	P50301,P50302,P50303,P50304,P50305,P50306,P50307,P50308,P50401,P50402,P50403,P50404,P50405,P50406,P50407,P50408,P50501,P50502,P50503,P50504,P50505,P50506,P50507,P50508, P50501S, P50502S, P50503S, P50504S, P50505S, P50506S, P50507S, P50508S, P50301S, P50302S, P50303S, P50304S, P50305S, P50306S, P50307S, P50308S,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, This is a reusable device, This is used for general plastic labware for mixing, transfer or storage of chemical or biological reagents. Can be used to hold liquid or solid samples or as a container for reactions. They are also used to collect filtrates from filtering operations as well as liquids from titrations. It is used for stirring the liquid,to hold liquid or solid samples or as a container for reactions. They are also used to collect filtrates from filtering operations as well as liquids from titrations. It is used for stirring the liquid. This is a reusable device.to hold liquid or solid samples or as a container for reactions. They are also used to collect filtrates from filtering operations as well as liquids from titrations. It is used for stirring the liquid. This is a reusable device	62011	Class A, All Others/ General IVDs	89041443CYLINDER023WT

15	Rackes & Boxes for IVD, Sterile/Non-sterile	<p>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, P20615, P20611, P20612, P20614, P20607, P20606, P20613, P10409, P10410, P20101, P20102, P20104, P20103, P20105, P20106, P20107, P11101, P11103, P20208, P20209, P20230, P20231, P20206, P20206A, P20207, P20207A, P20210, P11104, P11105, P11106, P11107, P20701, P20702, P20703, P20704, P20705, P20206, P20607, P20608, P20609, P20610, P20711, P20712, P20713, P20714, P20715, P20441, P20442, P20443, P20444, P20716, P20717, P20718, P20720, P20721, P20722, P20723, P20724, P20725, P20726, P20728, P20729, P50111, P50112, P50113, P50114, P70104, P70101, P70102, P20302, P20501, P20502, P20503, P20504, P90115, P90116, P70321, P70322, P70323, P70313, P70211, P70212, P70213, P70601, P70602, P70707, P70708, P70314, P70315, P70316, P70317, P70311, P70312, P70318, P11901, P11902, P11903, P11904, P11905, P11907, P11908, P70501, P70502, P70505, P70503, P70504, P70506, P10970, P40111, P70204, P70202, P106020, P70205, P10501, P10503, P70203, P70201, P90121, P90122, P90123, P90124, P90125, P90126, P90127, P90128, P90129, P90130, P90131, P11901S, P11902S, P11903S, P11904S, P11905Setc.....</p>	<p>Rack for Micro Centrifuge Tube, Centrifuge Tube Box, Click Together Conical Tube Racks, Universal Centrifuge Tube Rack, Foldable Space Saving Rack, Floating Rack for Micro Centrifuge Tube, Cryo Box, Single Hand Cryo Holder Rack, Cryo Box System 100 places, Cryo Cube Box / Storage Cube Box, Empty Micro Tip Gen 2 Boxes, PCR Workout Rack, PCR workstation rack with LID, Rotator Workstation, Multi Combination Racks, Expanding Tube Rack, Reversible Rack with Cover, Twisty Tube Rack, Frosty Mate Storage Racks, Frosty Mate Colour Change Racks, Test Tube Rack, Double Jumbo Test Tube Rack, Polygrid Test Tube Racks, Polywire Racks Delrin, Sharp Conainers, Coplin Jar, Slide Box/Tray/Mailer, Weighing Boats, Scoop/Spatulla, Sealing Mats/Films, Deep Well Plates/Reservoir, Safety Bottle Carier, etc..</p>	<p>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. (A device intended to be used on-board an in vitro diagnostic laboratory instrument or analyser to allow test tubes or vials of a nonstandard size to be placed onto an instrument/analyser test tube rack. It is typically made of plastic. This is a reusable device.)</p>	62010	Class A, All Others/ General IVDs	89041443RB025HD
16	Bottle & Carboys, Sterile/Non-sterile	<p>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, P11183, P11184, P11180A, P11181A, P11182A, P11183A, P11184A, P11515, P11516, P11517, P11518, P11519, P11520, P11521, P11522, P11523, P11511, P11512, P11513, P11510, P11191, P11192, P11200, P11301, P11302, P11305, P11306, P11307, P11308, P11311, P11312, P11313, P11314, P20511, P20512, P11139, P11149, P11159, P11159A, P11169, P11175, P11185, P11185A, P11183S, P11182S, P11162S, P11163S, P11184S, P90120, P90121, P90122, P90123, P90124, P90125, P90126, P90127, P90128, P90129, P90130, P90131 etc....</p>	<p>Narrow Mouth Bottle(PP, LDPE, HDPE), Narrow Mouth Bottle (Carboy Type), Wide Mouth Bottle(PP, LDPE, HDPE), Aspirator Bottle with Stopcock, Carboy, Carboy with Stopcock, Carboy with Mouth, Heavy Duty Wide Mouth Carboy with Stopcock, Spray Bottle, Dropping Bottle, Dropping Bottle Euro Type, Wash Bottle, Wash Bottle (Comet) etc.</p>	<p>is used to Storing of chemicals and reagents.</p>	63042	Class A, All Others/ General IVDs	89041443 BOTTLE026J8

17	Laboratory Instruments	<p>E11150,E11151,E11153,E11154,E11155,E11156,E11157,E11158,E10001,E10002,E10003,E10004,E10005,E10006,E10007,E10008,E10009,E10010,E11100,E11101,E11102,E11103,E11104,E11112,E11105,E11131,E11132,E11145,E11107,E11108,E11147,E11111,E11134,E11136,E11137,E11138,E11139,E11140,E11141,E11161,E11162,E11163,E11164,E11501,E11502,E11503,E11510,E11511,E11512,E11513,E11520,E11521,E11522,E11523,E11524,E11525,E11526,E11527,E11540,E11541,E11542,E11550,E11551,E11552,E11560,E11561,E11562,E11171,E11172D,E11173D,E11174D,E11175D,E11176D,E11177D,E11178D,E11179D,E11180D,E11181D,E11182D,E11183D,E11184D,E11185D,E11186D,E11187D,E111701,E111702,E111703,E111704,E111705,E111706,E111711,E111712,E111713,E111714,E111715,E11716,E11731,E11732,E11733,E11734,E11735,E11736,E11122,E11218,E11216,E11217,E11113,E11119,E11114,E11120,E11116,E11117,E11118,E12410,E12431,E12411,E12412,E12413,E12414,E12415,E12431,E12438,E12432,E12433,E12434,E12435,E12436,E12437,E12000,E12001,E12002,E12003,E12004,E12005,E12006,E12007,E12008,E12160,E12161,E12162,E12163,E12164,E12165,E12170,E12171,E12172,E12173,E12174,E12175,E12176,E12177,E12178,E12179,E12218,E12219,E12150,E12181,E12182,E12183,E12184,E12185,E12193,E12189,E12186,E12194,E12187,E12188,E12197,E12198,E12190,E12191,E12184,E12185,E12195,E12196,E12197,E12198,E12200,E12207,E12213,E12208,E12209,E12210,E12211,E12212,E12214,E12215,E12300,E12301,E12302,E12303,E12304,E12305,E12306,E12307,E12308,E12312,E12313,E12314,E12315,E12316,E12317,E12318,E12319,E12320,E12321,E12322,E12323,E12324,E12226,E12227,E12229,E12230,E12231,E12232,E12233,E12234,E12235,E12236,E12237,E12238,E12239,E12240,E12244,E12276,E12277,E12281,E12282,E12283,E12284,E12295,E12296,E12298,E12285,E12286,E12287,E12292,E12326,E12327,E12331,E12332,E12333,E12334,E12295,E12296,E12335,E12336,E12337,E12342,E12377,E12380,E12381,E12382,E12385,E12388,</p> <p>E11307,E11308,E11309,11231,E1234,E11232,E11233,E11224,E11650,E11651,E11652,E11653,E11654,E11235,E11236,E11230,E11330,E11360,E11370,E11380,E11390,E11331,E11332,E11333,E11334,E11335,E11336,E11337,E11338,E11339,E11368,E11361,E11362,E11363,E11364,E11365,E11366,E11367,E11340,E11341,E11342,E11343,E11344,E11345,E11346,E11347,E11348,E11358,E11349,E11350,E11310,E11311,E11321,E11322,E11312,E11313,E11314,E11315,E11316,E11317,E11318,E11319,E11320,E11323,E11324,E11325,E11326,E11327,E11190,E11191,E11192,E11193,E11194,E11195,E11196,E11197,E11198,E11200,E11201,E11202,E11300,E11301,E11302,E11303,E11270,E11271,E11272,E11273,E11274,P11305,E11301,E11302,E11303,E11280,E11281,E11282,E11283,E11284,E11285,E11286,E11274,E11495,E11451,E11452,E11453,E11415,E11416,E11417,E11418,E11419,E11895,E11260,E1261,E11262,E11290,E11291,E11460,E11480,E11490,E11411,E11413,E11414,E11355,E11356,E11357,E11920,E11925,E11928,E11929,E11930,E11931,E11932,E11933,E11934,E11935,E11936,E11937,E11938,E11339,E11940,E11941,E11942,E11943,E11944,E11948,E11949,E11950,E11951,E11800,E11801,E11806,E11810,E11815,E11816,E11821,E11823,E11824,E11825,E11826,E11830,E11601,E11602,E11603,E11604,E11605,E11606,E11607,E11608,E11609,E11610,E11611,E11612,E11620,E11621,E11622,E11623,E11624,E11617,E11618,E11619,E11613,E11614,E11615,E11616, Amber, Coloured etc...</p>	<p>Pipettes, Centrifuge Machines, Desiccators, Stepmate Stepper, Bottle Top Dispenser, Handheld Homogenizer, Flapping Homogenizer, Electrophoresis, Tube Roller, MAGNETIC STIRRERS & HOTPLATES, DIGITAL DRY BATH & THERMO MIX, etc... ROTATING MIXERS & SHAKERS, DIGITAL INCUBATORS OIL FREE VACUUM PUMPS</p>	<p>subsequent in vitro diagnostic processing and or testing, subsequent in vitro diagnostic processing and or testing. This is a bench top instruments used in centrifugation/heating/shaking, aspiration of liquid etc.. This is a reusable device</p>	62011	Class A, All Others/ General IVDs	89041443INSTRUMENT027 UD
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* 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 [Medical Device Regulations (SI 2002 n. 618, Reg. 7 (1) & Reg. (8) (1)]

Obelis U.K.

Date: 21/01/2025

Stamp:

OBELIS UK Ltd

Sandford Gate, East Point Business Park
OX4 6LB – Oxford

Annex F – List of facilities

1	Plot No-1, Shiv Ganga Industrial Estate, Lakheswari Bhagwanpur, Roorkee Pin-247667, Uttarakhand, India
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Obelis UK

Date: 21/01/2025

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