

E.A.R.-CERTIFICATE

(ART 10.3 of the Directive 98/79/EC on In Vitro Diagnostic)

REF. NO. : TMV 2498-2021

ORDER NO. : JC 1991-2021

DATE: 26/10/2021

MANUFACTURER: Abdos Labtech Private Limited
13A, Government Place
East, Kolkata, 700069, India

FACILITIES: Abdos Labtech Pvt. Ltd.
Plot No-1, Shiv Ganga
Industrial Estate, Lakeshwari,
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Pin-247667, India

PRODUCT CATEGORIES: Please See Annex A - List of Devices (17 Devices, 9 Pages)

MODELS: Please See Annex A - List of Devices (17 Devices, 9 Pages)

The European Authorized Representative Center Obelis s.a. declares that the aforementioned manufacturer has fulfilled the essential requirement of appointing a European Authorized Representative in accordance with article 10.3 of the Directive 98/79/EC and to the terms and conditions set out in the agreement entered into force on 01/05/2016.*



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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 certificate is not a confirmation of product notification nor an approval to place products on the market.
**This certificate will become void automatically upon termination of the EAR agreement.

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



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Annex A - List of Devices

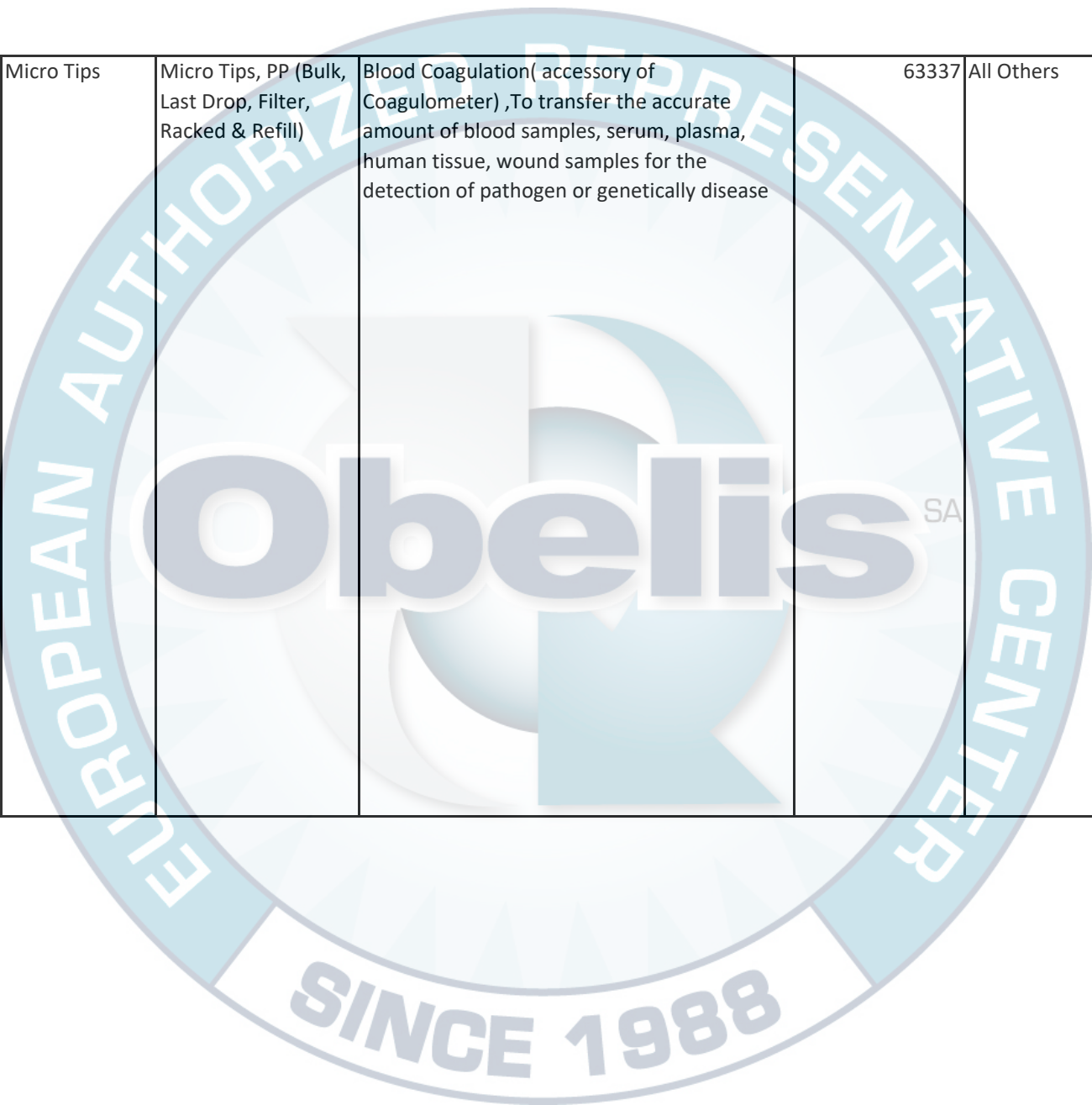
(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN Code	Class
1	P10201, P10202, P10203, P10207, P10201A, P10204, P10204A, P10205, P10203A,P10208,P10209,P10210, etc..	Micro Centrifuge Tube	Micro Centrifuge Tubes (Natural, Coloured ,Amber & Last Drop)	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	All Others

2	P10430, P10401,P10441 ,P10431,P1040 3,P10443,P104 05, P10407,P10405 T, P10407T,P1043 2,P10423, P10449, P10411, P10413, P10415, P10417,P10480 , P10481, P10483, P10487, P10484, P10486,R,G,B, etc	Centrifuge Tube	Centrifuge Tube, Conical/Self Stand (Natural/ Amber)	Hematocrite Centrifuge, To centrifuge the large volume of blood samples, serum, plasma, human tissue, wound samples for the detection of pathogen or genetically disease	43761	All Others
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3	P10402, P10442, P10404, P10444, P10406, P10408, P10406T, P10408T, P10419,P10421 , P10424,P10450 , P10425, P10451,P10426 ,P10452,P1042 7, P10453, P10412,P10414 , P10418, P10482, P10485, P10488, R,G,B, etc	Centrifuge Tube	Centrifuge Tube, Conical/Self Stand (Natural/ Amber) Sterile	Hematocrite Centrifuge, To centrifuge the large volume of blood samples, serum, plasma, human tissue, wound samples for the detection of pathogen or genetically disease	58970	All Others
4	P21020, P21022, P21025,P21026 , P21014, P21023, P21031, P21033, P21026 etc..	Tissue Culture Treated Plates	Tissue Culture Plates/Culture, PS	Diagnosis of Lymes/ELISA/RIA, For the culturing of the blood samples, serum, plasma, human tissue, wound samples, urine samples, human excreta for the enumeration of numbers , detection of pathogen/ species & antibiotic sensitivity of the pathogen	17440	All Others

5	P10115, P10137, P10130, P10101, P10105, P10138, P10102, 10106, P10144, P10145, P10116, P10139, P10140, P10141, P10107,P10108 , P10142, P10109, P10110, P10117, P10147, P10149, P10148, P10111, P10112, P10150, P10113, P10114	Micro Tips	Micro Tips, PP (Bulk, Last Drop, Filter, Racked & Refill)	Blood Coagulation(accessory of Coagulometer) ,To transfer the accurate amount of blood samples, serum, plasma, human tissue, wound samples for the detection of pathogen or genetically disease	63337	All Others
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6	P10707,P10706 ,P10701,P10702,P10713,P10717, P10713, P10715, P10723, P10709, P10708 etc..	PCR Tubes	PCR Tubes (Plates) PP	For the isolation & detection of blood, detection of pathogen/ species & antibiotic sensitivity of the pathogen, DNA, RNA detectio/Blood Coagulation	61304	All Others
7	P10901,P10902 ,P10903,P1094, P10905,P10906 ,P10907,P10908,P10909,P0911,P10912,P10928,P10927,P10931,P10935,P10937,P10934,P10915,P10920,P10924,P109226 etc..	Petri Dish	Petridish , PS	Diagnosis of Lymes/ELISA/RIA, For the culturing of the blood samples, serum, plasma, human tissue, wound samples, urine samples, human excreta for the enumeration of numbers , detection of pathogen/ species & antibiotic sensitivity of the pathogen	43344	All Others
8	P10303, P10306,P10301 , P10305, P10301A, P10301A1, P10305A, P10305A1 etc..	RIA Vial	RIA Vial , PP/PS	Hematocrite tubes in diagnosis of Lymes/ ELISA/RIA, For the sample preparation of blood samples, serum, plasma, human tissue, wound samples for the detection of pathogen or genetically disease	43324	All Others

9	P21070,P21072 ,P21071 etc..	Bioreaction Tube	Bioreaction Tube , PP/HDPE	Hematocrite tubes in diagnosis For the culturing of the blood /Urine samples, serum, plasma, human tissue, wound samples, urine samples, human excreta for the enumeration of numbers , detection of pathogen/ species & antibiotic sensitivity of the pathogen	64705	All Others
10	P10304, P10307 , P10302, P10312,P10313 , A, A1, R,B,G,Y, etc.	RIA Vial Cap	Radioimmunoassay (RIA) Vial Cap PP/HDPE/LDPE	Hematocrite tubes in diagnosis of Lymes/ ELISA/RIA, For the sample preparation of blood samples, serum, plasma, human tissue, wound samples for the detection of pathogen or genetically disease	43324	All Others
11	P40101,P40105 ,P40103,P4011 2, R, B,W, etc	Sample Container	Sample Container, PP/HDPE	Hematocrite ,For the sample collection of blood, serum, plasma, Tissues, wound samples, Urine for the detection of pathogen or genetically diseases	46023	All Others

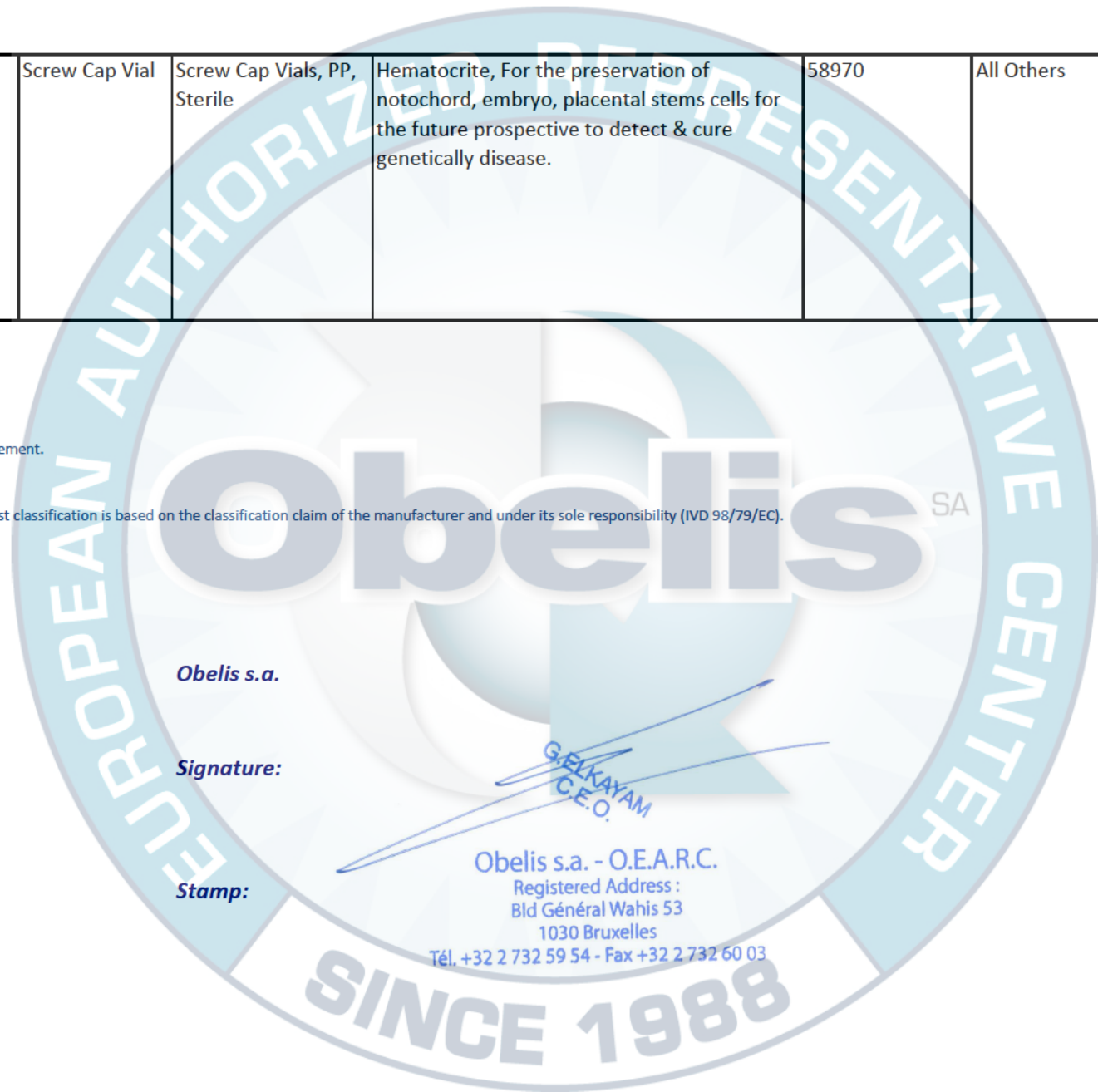
12	P40102, P40106,P40104 , P40113, P40109,P40110 , R, B,W, etc	Sample Container	Sample Container, PP/HDPE, Sterile	Hematocrite ,For the sample collection of blood, serum, plasma, Tissues, wound samples, Urine for the detection of pathogen or genetically diseases	46023	All Others
13	P60115 P60116 P60117 P60118	Cryo Vial External Thread	Cryo Vial External Threaded Sterile, PP	Hematocrite, For the preservation of notochord, embryo, placental stems cells for the future prospective to detect & cure genetically disease.	65457	All Others
14	P60108 P60109 P60110 P60112 P60113	Cryo Vial Internal Thread	Cryo Vial Internal Threaded Sterile with Silicone Seal, PP	Hematocrite, For the preservation of notochord, embryo, placental stems cells for the future prospective to detect & cure genetically disease.	65457	All Others

<p>15</p>	<p>P60102,P60103 , P60102NP, NPNS, P60119, P60106, P60107, P60119A, P60119A1, P60106A, P60106A1, P60107A, P60107A1, P60104 R,B,Y,G,W,P60114 R,B,W,G,Y,P60107S, etc</p>	<p>Freezing Tubes</p>	<p>Freezing Tubes(Storage Vial)</p>	<p>Hematocrite, For the preservation of notochord, embryo, placental stems cells for the future prospective to detect & cure genetically disease.</p>	<p>65457</p>	<p>All Others</p>
<p>16</p>	<p>P10224, P10223, P10232, P10232, P10240, P10241, P10228, P10229, R,B,Y,G,A</p>	<p>Screw Cap Vial</p>	<p>Screw Cap Vials, PP</p>	<p>Hematocrite, For the preservation of notochord, embryo, placental stems cells for the future prospective to detect & cure genetically disease.</p>	<p>43761</p>	<p>All Others</p>

<p>17</p> <p>P10224, P10223, P10232, P10232, P10240, P10241, P10228, P10229, R,B,Y,G,A</p>	<p>Screw Cap Vial</p>	<p>Screw Cap Vials, PP, Sterile</p>	<p>Hematocrite, For the preservation of notochord, embryo, placental stems cells for the future prospective to detect & cure genetically disease.</p>	<p>58970</p>	<p>All Others</p>
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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 (IVD 98/79/EC).



Obelis s.a.

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Stamp:

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