

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.
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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

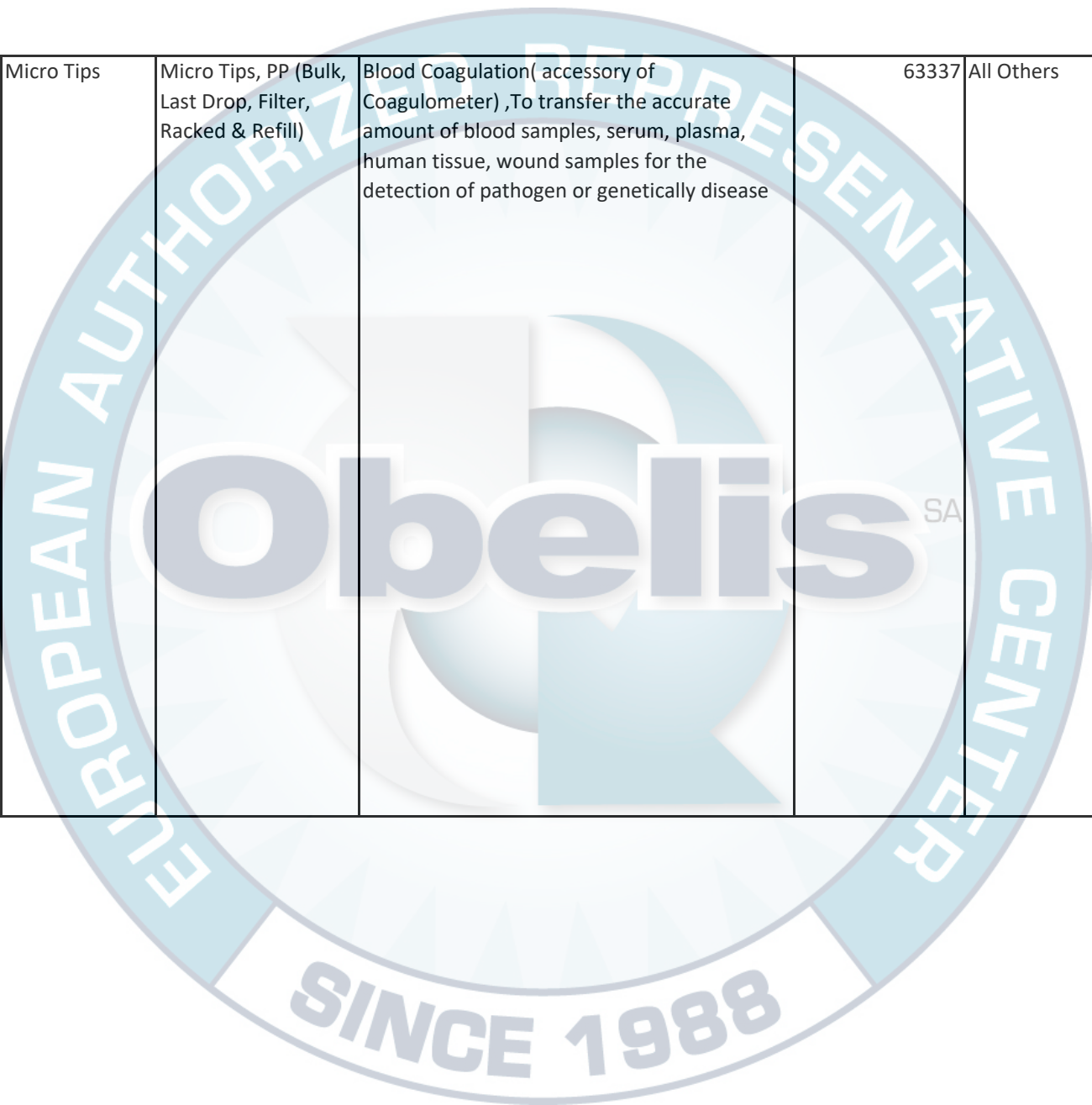
(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

| # | 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 |
|---|---|-----------------|--|---|-------|------------|

| | | | | | | |
|---|---|----------------------------------|---|--|-------|------------|
| 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 |
|---|--|------------|---|--|-------|------------|



| | | | | | | |
|---|--|------------|-----------------------|---|-------|------------|
| 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,P10922 6 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 |

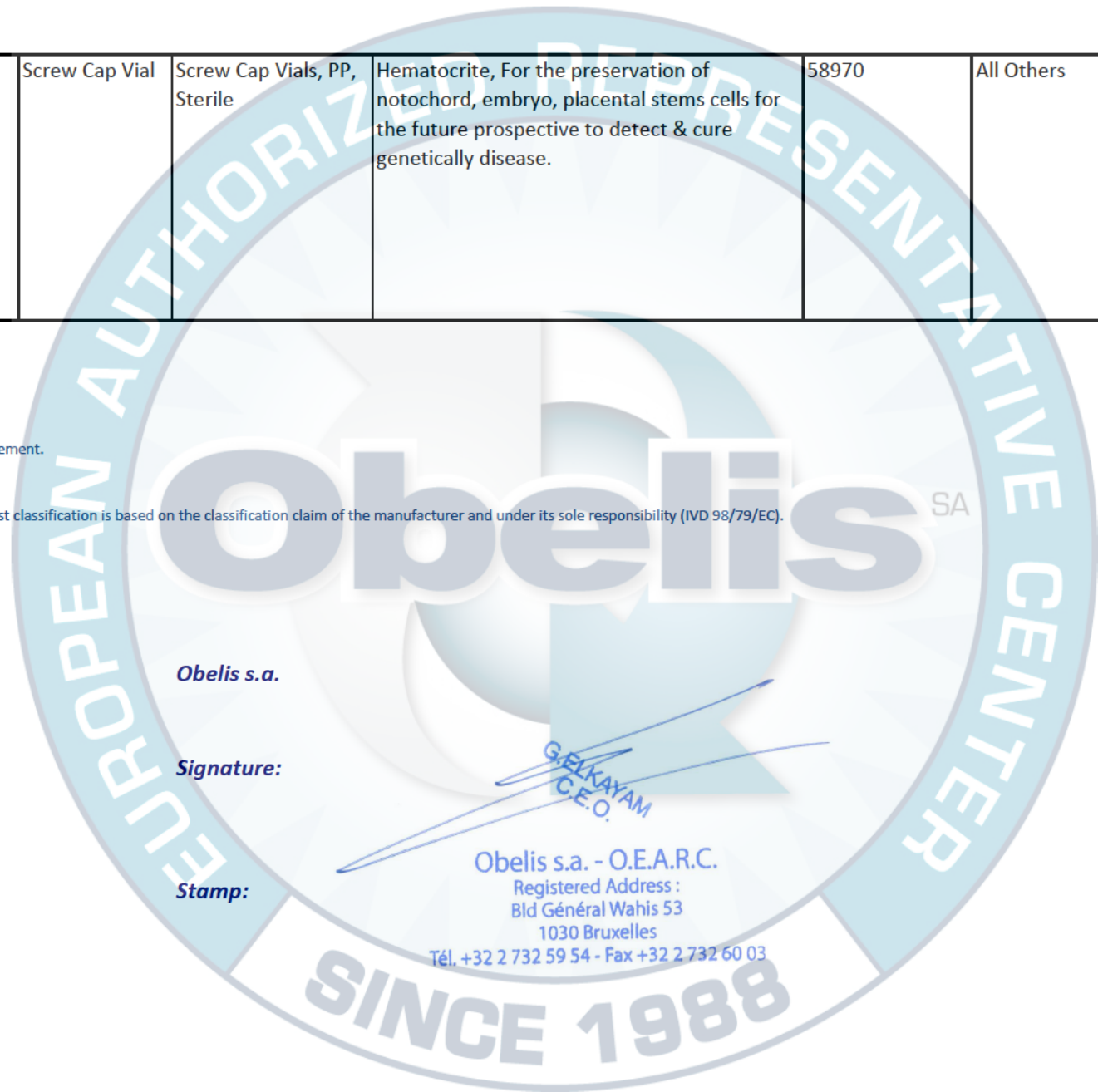
| | | | | | | |
|----|---|------------------------------|--|--|-------|------------|
| 12 | P40102, P40106,P40104 , P40113, P40109,P40110 , R, B,W, etc | Sample Container | Sample Container, PP/HDPE, Sterile | Hematocrite ,For the sample collection of blood, serum, plasma, Tissues, wound samples, Urine 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 |

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|-----------|--|-----------------------|-------------------------------------|---|--------------|-------------------|
| <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> |
|--|-----------------------|---|---|--------------|-------------------|

* 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).



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Stamp:

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