

E.A.R.-CERTIFICATE

(ARTICLE 11.2 OF THE REGULATION (EU) 2017/746 ON IN VITRO DIAGNOSTIC MEDICAL DEVICES)

REFERENCE NO.: TMV 0229-2022

ORDER NO.: JC 2529-2021

DATE: 16/03/2022

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, Bhagwanpur,
Roorkee Pin-247667, Uttarakhand,
India

PRODUCT CATEGORIES: Please See Annex A - List of Devices (20 Devices, 8 Pages)

MODELS: Please See Annex A - List of Devices (20 Devices, 8 Pages)

The European Authorized Representative Center Obelis s.a. declares it will assume the role of European Authorised Representative of the aforementioned manufacturer, provided that the manufacturer complied with the terms and conditions set out in the EAR Services Agreement, which entered into force on 01/11/2021*, and the Mandate is signed by both parties in accordance with article 11.2 of the IVDR - Regulation (EU) 2017/746.



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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.

*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 or rejection of the products from Obelis PRRC

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



ANNEX to IVDR EAR Certificate

Manufacturer: Abdos Labtech Pvt. Ltd.

Country: India

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#	GMDN/ EMDN	Generic device name (including BASIC UDI)	Commercial Name of device	Intended use	Class	Rule	Legacy (Y/N)	Mandated (Y/N)	Mandate starting date	Mandated Vigilance (Y/N)
1	43761	Micro Centrifuge Tubes, 89041443MCT001FU	Micro Centrifuge Tubes	Hematocrite Centrifuge, To centrifuge the small volume of blood samples, serum, plasma, human tissue, wound samples for the detection of pathogen or genetically disease	A	5	N	N	N/A	N
2	43761	Centrifuge Tube, 89041443CT002FS	Centrifuge Tube	Hematocrite Centrifuge, To centrifuge the large volume of blood samples, serum, plasma, human tissue, wound samples for the detection of	A	5	N	N	N/A	N

				pathogen or genetically disease						
3	58970	Centrifuge Tube, 89041443CT002FS	Centrifuge Tube, 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	A sterile	5	Y	N	N/A	N
4	17440	Tissue Culture Treated Plate, 89041443CELLCULT URE013YN	Tissue Culture Treated Plate Sterile	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, Hematocrite diagnosis	A sterile	5	Y	N	N/A	N
5	63337	Micro Tips, 89041443TIPS006U D	Micro Tips	Blood Coagulation(accessory of Coagulometer) ,To transfer the accurate amount of blood	A	5	N	N	N/A	N

				samples, serum, plasma, human tissue, wound samples for the detection of pathogen or genetically disease						
6	61304	PCR Tubes, 89041443PCR011G Q	PCR Tubes (Plates)	For the isolation & detection of blood, detection of pathogen/ species & antibiotic sensitivity of the pathogen, DNA, RNA detection/Blood Coagulation, Hematocrite diagnosis	A	5	N	N	N/A	N
7	43344	Petridish, 89041443PETRIDIS H0095S	Petridish	Hematocrite 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	A	5	N	N	N/A	N

8	43324	Rial Vial, 89041443RIAVIALS 008VJ	RIA Vial	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	A	5	N	N	N/A	N
9	43324	RIA Vial Cap, 89041443RIAVIALS 008VJ	RIA Vial Cap	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	A	5	N	N	N/A	N
10	64705	Bioreaction Tube, 89041443BIOREAC TION010PP	Bioreaction Tube Sterile	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	A sterile	5	Y	N	N/A	N

				& antibiotic sensitivity of the pathogen						
11	46023	Sample container, 89041443SAMPLEC ONT007ZD	Sample Container	Hematocrite ,For the sample collection of blood, serum, plasma, Tissues, wound samples, Urine for the detection of pathogen or genetically diseases	A	5	N	N	N/A	N
12	46023	Sample container, 89041443SAMPLEC ONT007ZD	Sample Container Sterile	Hematocrite ,For the sample collection of blood, serum, plasma, Tissues, wound samples, Urine for the detection of pathogen or genetically diseases	A sterile	5	Y	N	N/A	N
13	65457	Cryo Vial External, 89041443CRYO004 R4	Cryo Vial External Sterile	Hematocrite ,For the preservation of notochord, embryo, placental stems cells for the future prospective to detect & cure genetically disease.	A sterile	5	Y	N	N/A	N
14	65457	Cryo Vial Internal, 89041443CRYO004 R4	Cryo Vial Internal Sterile	Hematocrite ,For the preservation of notochord, embryo, placental stems cells for the future prospective to detect	A sterile	5	Y	N	N/A	N

				& cure genetically disease.						
15	65457	Freezing tube, 89041443FREEZING 003UV	Freezing Tube Sterile	Hematocrite ,For the preservation of notochord, embryo, placental stems cells for the future prospective to detect & cure genetically disease.	A sterile	5	Y	N	N/A	N
16	43761	Screw Cap Vial, 89041443SCREWCA PVIAL012QK	Screw Cap Vial	Hematocrite ,For the preservation of notochord, embryo, placental stems cells for the future prospective to detect & cure genetically disease.	A	5	N	N	N/A	N
17	58970	Screw Cap Vial, 89041443SCREWCA PVIAL012QK	Screw Cap Vial, Sterile	Hematocrite ,For the preservation of notochord, embryo, placental stems cells for the future prospective to detect & cure genetically disease.	A sterile	5	Y	N	N/A	N
18	63337	Micro Tips, 89041443TIPS006U D	Micro Tips Sterile	Blood Coagulation(accessory of Coagulometer) ,To transfer the accurate amount of blood samples, serum, plasma, human tissue, wound samples for the	A sterile	5	Y	N	N/A	N

				detection of pathogen or genetically disease						
19	65457	Storage Vial, 89041443STORAGE 005GD	Storage Vial	Hematocrite ,For the preservation of notochord, embryo, placental stems cells for the future prospective to detect & cure genetically disease.	A	5	N	N	N/A	N
20	43344	Petridish, 89041443PETRIDIS H0095S	Petridish Sterile	Hematocrite 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	A sterile	5	Y	N	N/A	N

Date: 16/03/2022

CEO Of Obelis

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