अनुबंध|Contract

अनुबंध क्रमांक|Contract No: GEMC-511687748201432
अनुबंध तिथि|Generated Date : 26-Mar-2025
बोली/आरए/पीबीपी संख्या|Bid/RA/PBP No.: GEM/2024/B/5544947

अनुसूची नाम|Schedule Name: Schedule 4,Schedule 1,Schedule 2,Schedule 9,Schedule 3,Schedule 7

संगठन विवरण|Organisation Details

प्ररूप|Type :	Central PSU
मंत्रालय|Ministry :	Ministry of Coal
विभाग|Department :	COAL INDIA LIMITED
संगठन का नाम|Organisation Name :	Mahanadi Coalfields Limited
कार्यालय क्षेत्र|Office Zone:	MCL Sambalpur Odisha

खरीदार विवरण|Buyer Details

पद|Designation :	Shivendra Vyas Asst Manager MM
संपर्क नंबर|Contact No. :	-9549295368-
ईमेल आईडी|Email ID :	mmpur1d.mcl@coalindia.in
जीएसटीआईएन|GSTIN :	-
पता|Address :	MAHANADI COALFIELDS LIMITED, PO - JAGRUTI VIHAR, BURLA, SAMBALPUR, ODISHA-768020, India

वित्तीय स्वीकृति विवरण|Financial Approval Detail

आईएफडी सहमति|IFD Concurrence :	No
प्रशासनिक अनुमोदन का पदनाम| Designation of Administrative Approval:	GM (MM)/HoD
वित्तीय अनुमोदन का पदनाम| Designation of Financial Approval :	AF(MM)

भुगतान प्राधिकरण विवरण|Paying Authority Details

Role:	PAO
भुगतान का तरीका| Payment Mode:	Offline
पद|Designation :	B Narasimha AM F
ईमेल आईडी|Email ID :	nb.basanaboina@coalindia.in
जीएसटीआईएन|GSTIN :	21AABCM5188P1Z3
पता|Address:	MAHANADI COALFIELDS LIMITED, AT /PO - JAGRUTI VIHAR, BURLA, SAMBALPUR, ODISHA-768020, India

विक्रेता विवरण|Seller Details

जेम विक्रेता आईडी|GeM Seller ID :	OL9F210003877965
कंपनी का नाम|Company Name :	SUNWEST BIO MEDICAL PRIVATE LIMITED
संपर्क नंबर|Contact No. :	09873914444
ईमेल आईडी|Email ID :	sunwestbiomedicalpvtltd@gmail.com
पता| Address :	Plot No - 114,,Sector-7, Village/Town:- IMT Manesar, City:- Gurgaon,Sector-7, Village/Town:- IMT Manesar, City:- Gurgaon,Sector-7, Village/Town:- IMT Manesar, City:- Gurgaon, Gurgaon, HARYANA-122050, India
एमएसएमई पंजीकरण संख्या|MSME Registration number :	UDYAM-HR-05-0025016
जीएसटीआईएन|GSTIN:	06ABFCS9428R1ZG (R) , (M)
एमएसई सामाजिक श्रेणी|MSE Social Category :	General
एमएसई लिंग श्रेणी|MSE Gender :	Male

*जिसके नाम के पक्ष में GST/TAX इनवॉइस पेश किया जाएगा|GST / Tax invoice to be raised in the name of - Consignee

वितरण निर्देश | Delivery Instructions : NA

उत्पाद विवरण|Product Details

#	आइटम विवरण|Item Description	आइटम विवरण| Ordered Quantity	इकाई | Unit	इकाई मूल्य (INR)| Unit Price (INR)	कर विभाजन (INR)| Tax Bifurcation (INR)	मूल्य (INR में सभी शुल्क और कर सहित)| Price (Inclusive of all Duties and Taxes in INR)
1	**उत्पाद का नाम |Product Name :** Sunsure Syphilis Antibody Rapid Test Kit **ब्रांड|Brand :** Sunsure **ब्रांड प्रकार|Brand Type :** Registered Brand **कैटलॉग की स्थिति|Catalogue Status:** OEM verified catalogue **कैसे बेचा जा रहा है|Selling As :** OEM **श्रेणी का नाम और चतुर्थांश|Category Name & Quadrant :** Syphilis Rapid Test Kits (Q2) **मॉडल|Model:** SUNSURE **एचएसएन कोड|HSN Code:** HSN not specified by seller	300	Test	5.98	NA	1,794
2	**उत्पाद का नाम |Product Name :** Sunsure Dengue NS1 Antigen and IgM + IgG Antibodies Detection Rapid Test Kit **ब्रांड|Brand :** Sunsure **ब्रांड प्रकार|Brand Type :** Registered Brand **कैटलॉग की स्थिति|Catalogue Status:** OEM verified catalogue **कैसे बेचा जा रहा है|Selling As :** OEM **श्रेणी का नाम और चतुर्थांश|Category Name & Quadrant :** Dengue Rapid Test Kits (Q2) **मॉडल|Model:** Sunsure Dengue Combo **एचएसएन कोड|HSN Code:** HSN not specified by seller	300	Test	28.9	NA	8,670
	उत्पाद का नाम |Product Name : Sunsure Malaria Rapid Test Kit **ब्रांड|Brand :** Sunsure					

3	**ब्रांड प्रकार|Brand Type :** Registered Brand **कैटलॉग की स्थिति|Catalogue Status:** OEM verified catalogue **कैसे बेचा जा रहा है|Selling As :** OEM **श्रेणी का नाम और चतुर्थांश|Category Name & Quadrant :** Malaria Rapid Test Kits (Q2) **मॉडल|Model:** SUNSURE **एचएसएन कोड|HSN Code:** HSN not specified by seller	300	Test	9.38	NA	2,814
4	**उत्पाद का नाम |Product Name :** Sunsure HBsAg Rapid Test Kit **ब्रांड|Brand :** Sunsure **ब्रांड प्रकार|Brand Type :** Registered Brand **कैटलॉग की स्थिति|Catalogue Status:** OEM verified catalogue **कैसे बेचा जा रहा है|Selling As :** OEM **श्रेणी का नाम और चतुर्थांश|Category Name & Quadrant :** HBsAg Rapid Test Kits (Q2) **मॉडल|Model:** SUNSURE **एचएसएन कोड|HSN Code:** HSN not specified by seller	500	Test	5.15	NA	2,575
5	**उत्पाद का नाम |Product Name :** Sunsure Salmonella Typhi IgM and IgG Antibodies Detection Rapid Test Kit **ब्रांड|Brand :** Sunsure **ब्रांड प्रकार|Brand Type :** Registered Brand **कैटलॉग की स्थिति|Catalogue Status:** OEM verified catalogue **कैसे बेचा जा रहा है|Selling As :** OEM **श्रेणी का नाम और चतुर्थांश|Category Name & Quadrant :** Typhoid Rapid Test Kits (Q2) **मॉडल|Model:** SUNSURE **एचएसएन कोड|HSN Code:** HSN not specified by seller	300	Test	10.4	NA	3,120
6	**उत्पाद का नाम |Product Name :** Sunsure Pregnancy Rapid Test Kit **ब्रांड|Brand :** Sunsure **ब्रांड प्रकार|Brand Type :** Registered Brand **कैटलॉग की स्थिति|Catalogue Status:** OEM verified catalogue **कैसे बेचा जा रहा है|Selling As :** OEM **श्रेणी का नाम और चतुर्थांश|Category Name & Quadrant :** Pregnancy Rapid Test Kits (V2) (Q2) **मॉडल|Model:** Sunsure **एचएसएन कोड|HSN Code:** HSN not specified by seller	300	Test	3.58	NA	1,074
कुल ऑर्डर मूल्य |Total Order Value (in INR)						**20,047**

परेषिती विवरण|Consignee Detail

क्र.सं.|S.No	परेषिती|Consignee	वस्तु|Item	लॉट नंबर| Lot No.	मात्रा|Quantity	दिनांक के बाद डिलीवरी शुरू करना है| Delivery Start After	वितरण पूरा कब तक करना है| Delivery To Be Completed By
1	पद| Designation : - ईमेल आईडी|Email ID : kunachandra.polai@nic.in संपर्क|Contact : 0663-2542560- जीएसटीआईएन|GSTIN : 21AABCM5188P1Z3 पता|Address : Anand Vihar Hospital, At/Po: Jagriti Vihar, Burla, Sambalpur-768020, Sambalpur, ODISHA-768020, India	Sunsure Syphilis Antibody Rapid Test Kit	-	300	26-Mar-2025	25-Apr-2025
		Sunsure Dengue NS1 Antigen and IgM + IgG Antibodies Detection Rapid Test Kit	-	300	26-Mar-2025	25-Apr-2025
		Sunsure Malaria Rapid Test Kit	-	300	26-Mar-2025	25-Apr-2025
		Sunsure HBsAg Rapid Test Kit	-	500	26-Mar-2025	25-Apr-2025
		Sunsure Salmonella Typhi IgM and IgG Antibodies Detection Rapid Test Kit	-	300	26-Mar-2025	25-Apr-2025
		Sunsure Pregnancy Rapid Test Kit	-	300	26-Mar-2025	25-Apr-2025

Product Specification for Sunsure Syphilis Antibody Rapid Test Kit

विनिर्देश|Specification	उप-विनिर्देश|Sub-Spec	मूल्य|Value
GENERAL FEATURES	Product Description	Syphilis Rapid Test Kit
	Clinical Purpose	To provide a quick and accurate diagnosis of syphilis infection in all stages of infection by detecting antibodies to Treponema Pallidum
	Type of Kit	Syphilis Antibody Rapid Test Kit
	Detects	Total Anti-Treponema Pallidum Antibody (IgG,IgM & IgA)
	Detection Type	Qualitative

PRODUCT INFORMATION	The assay shall have solid phase coated with synthetic or recombinant type of Treponema Pallidum antigens	Yes
	Testing Principle	Lateral Flow Immunochromatographic Assay
	Species Reactivity	Human
	Type of Sample	Serum,Plasma
	Time to Result	≤ 30 minutes
	Ability to evaluate negative or positive test result	Yes
	Sensitivity	≥99%
	Specificity	≥98%
	Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature	Yes
	The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer	Yes
	Contains an internal control dot/band for the confirmation that the test has been performed correctly	Yes
	The control dot/band able to detect the presence of human immunoglobulin and not be just a procedural control or meant merely for checking the flow of reagents or integrity of antigens except in lateral flow technology	Yes
	Maintenance of cold chain by the supplier during storage and transportation of Kits at 2°C to 8°C and placement of cumulative time temperature indicator technology on every pack of kits	Yes
KIT CONTENTS	Kit Contents	Test Card/Cassette with Desiccant, Sample Dropper, Assay Buffer (if any)
	All the components shall be in the quantity as per pack size	Yes
	Adequate document detailing principle, components, methodologies, validity criteria, interpretation of results, performance characteristics, bio-safety, limitations of assay, storage condition, mfg & exp date and method of disposal provided with kit	Yes
	Positive and negative controls provided with each pack of kit	Yes
	Quantity of positive and negative controls provided	Sufficient for conducting 20% of the tests (10% negative and 10% positive controls)
	Each test card/strip supplied with sterile auto retractable disposable lancet and disposable alcoholic swabs	Yes
PACKAGING	Pack size of kit	50 Tests
	The test kit packed in such a way that there is proivision to conduct single test at a time	Yes
	Each test card/cassette with desiccant individually packed in a hermetically sealed and non-permeable pouch	Yes
CERTIFICATIONS & REPORTS	Compliance with Medical Device Rule (MDR) 2017 as amended till date	Yes
	Availability of valid drug license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules there under as amended till date	Yes
	Valid Drug License Number	MFG/IVD/2023/000157
	Manufacturing unit certification	ISO:13485 (Latest)
	Additional voluntary certification available	CE
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission or along with supplies as per buyer requirement	Yes
SHELF LIFE	Shelf life in months from the date of manufacture	24
	Minimum shelf life of the product at the time of delivery to the consignee	3/4 th of Total Shelf Life
ADVANCE SAMPLE	Agree to provide advance sample of the product for buyer's approval before commencement of supply in case of bidding	Yes
ADDITIONAL REQUIREMENT	Additional Requirement	NA

Product Specification for Sunsure Dengue NS1 Antigen and IgM + IgG Antibodies Detection Rapid Test Kit

विनिर्देश|Specification	उप-विनिर्देश|Sub-Spec	मूल्य|Value
GENERAL FEATURES	Product Description	Dengue Rapid Test Kit
	Clinical Purpose	To diagnose dengue virus infection in a patient's blood sample

PRODUCT INFORMATION	Type of Kit	Dengue NS1 Antigen and IgM + IgG Antibodies Detection Rapid Test Kit
	Detection Type	Qualitative
	Kit should be able to detect all the 4 serotypes of dengue viruses (DEN-1, DEN-2, DEN-3, and DEN-4)	Yes
	The test should be able to differentially detect IgG and IgM Antibodies against all 4 serotypes of Dengue virus	Yes
	Test should have no cross reactivity with other Flavivirus group mediated and mosquitoes-borne disease	Yes
	Testing Principle	Lateral Flow Immunochromatographic Assay
	Species Reactivity	Human
	Type of Sample	Whole Blood,Serum,Plasma
	Time to Result	≤ 30 minutes
	Ability to evaluate negative or positive test result	Yes
	Sensitivity for Dengue NS1 Ag (%)	≥ 95%
	Specificity for Dengue NS1 Ag (%)	≥ 99%
	Sensitivity for Dengue IgM/IgG Antibody (%)	≥ 94%
	Specificity for Dengue IgM/IgG Antibody (%)	≥ 96%
	Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature	Yes
	Contains an internal control dot/band for the confirmation that the test has been performed correctly	Yes
	The control dot/band able to detect the presence of human immunoglobulin and not be just a procedural control or meant merely for checking the flow of reagents or integrity of antigens except in lateral flow technology	Yes
	Maintenance of cold chain by the supplier during storage and transportation of Kits at 2°C to 8°C and placement of cumulative time temperature indicator technology on every pack of kits	Yes
KIT CONTENTS	Kit Contents	Test Card/Cassette with Desiccant, Sample Dropper, Assay Buffer (if any)
	All the components shall be in the quantity as per pack size	Yes
	Adequate document detailing principle, components, methodologies, validity criteria, interpretation of results, performance characteristics, bio-safety, limitations of assay, storage condition, mfg & exp date and method of disposal provided with kit	Yes
	Positive and negative controls provided with each pack of kit	Yes
	Quantity of positive and negative controls provided	Sufficient for conducting 20% of the tests (10% negative and 10% positive controls)
PACKAGING	Pack size of kit	10 Tests
	The test kit packed in such a way that there is proivision to conduct single test at a time	Yes
	Each test card/cassette with desiccant individually packed in a hermetically sealed and non-permeable pouch	Yes
CERTIFICATIONS & REPORTS	Compliance with Medical Device Rule (MDR) 2017 as amended till date	Yes
	Availability of valid drug license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Valid Drug License Number	MFG/IVD/2023/000157
	Manufacturing unit certification	ISO:13485 (Latest)
	Additional voluntary certification available	CE
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission or along with supplies as per buyer requirement	Yes
SHELF LIFE	Shelf life in months from the date of manufacture	24
	Minimum shelf life of the product at the time of delivery to the consignee	3/4 th of Total Shelf Life
ADVANCE SAMPLE	Agree to provide advance sample of the product for buyer's approval before commencement of supply in case of bidding	Yes
ADDITIONAL REQUIREMENT	Additional Requirement	NA

Product Specification for Sunsure Malaria Rapid Test Kit

विनिर्देश|Specification	उप-विनिर्देश|Sub-Spec	मूल्य|Value
GENERAL FEATURES	Product Description	Malaria Rapid Test Kit
	Clinical Purpose	To provide early diagnosis of Malaria infection
PRODUCT INFORMATION	Test differentially detects	Antigen of P.Falciparum (HRP-2/ LDH) and Pan Plasmodia against P.falciparum, P.vivax, P.ovale, P.malariae (LDH) from human serum or plasma or whole blood
	The test should be based on the principle of capture of parasite antigen from blood using monoclonal antibodies specific for antigen target	Yes
	Detection Type	Qualitative
	Testing Principle	Lateral Flow Immunochromatographic Assay
	Species Reactivity	Human
	Type of Sample	Whole Blood,Serum,Plasma
	Time to Result	≤ 30 minutes
	Ability to evaluate negative or positive test result	Yes
	Sensitivity	≥99%
	Specificity	≥98%
	Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature	Yes
	Contains an internal control dot/band for the confirmation that the test has been performed correctly	Yes
	The control dot/band able to detect the presence of human immunoglobulin and not be just a procedural control or meant merely for checking the flow of reagents or integrity of antigens except in lateral flow technology	Yes
	Maintenance of cold chain by the supplier during storage and transportation of Kits at 2°C to 8°C and placement of cumulative time temperature indicator technology on every pack of kits	Yes
KIT CONTENTS	Kit Contents	Test Card/Cassette with Desiccant, Sample Dropper, Assay Buffer (if any)
	All the components shall be in the quantity as per pack size	Yes
	Adequate document detailing principle, components, methodologies, validity criteria, interpretation of results, performance characteristics, bio-safety, limitations of assay, storage condition, mfg & exp date and method of disposal provided with kit	Yes
	Positive and negative controls provided with each pack of kit	Yes
	Quantity of positive and negative controls provided	Sufficient for conducting 20% of the tests (10% negative and 10% positive controls)
PACKAGING	Pack size of kit	50 Tests
	The test kit packed in such a way that there is proivision to conduct single test at a time	Yes
	Each test card/cassette with desiccant individually packed in a hermetically sealed and non-permeable pouch	Yes
CERTIFICATIONS & REPORTS	Compliance with Medical Device Rules (MDR) 2017 as amended till date	Yes
	Availability of valid drug license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Valid Drug License Number	MFG/IVD/2023/000157
	Manufacturing unit certification	ISO:13485 (Latest)
	Additional voluntary certification available	CE
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission or along with supplies as per buyer requirement	Yes
SHELF LIFE	Shelf life in months from the date of manufacture	24
	Minimum shelf life of the product at the time of delivery to the consignee	3/4 th of Total Shelf Life
ADVANCE SAMPLE	Agree to provide advance sample of the product for buyer's approval before commencement of supply in case of bidding	Yes
ADDITIONAL REQUIREMENT	Additional Requirement	NA

Product Specification for Sunsure HBsAg Rapid Test Kit

विनिर्देश|Specification	उप-विनिर्देश|Sub-Spec	मूल्य|Value
GENERAL FEATURES	Product Description	HBsAg Rapid Test Kit
	Clinical Purpose	To provide diagnosis of Hepatitis B Virus infection
PRODUCT INFORMATION	Detects	Hepatitis B Surface Antigen (HBsAg)
	Should be solid phase/ particle coated with monoclonal antibodies to HBsAg	Yes
	Test Should be able to detect all 11 subtype and Variants of HBsAg	Yes
	Detection Type	Qualitative
	Testing Principle	Lateral Flow Immunochromatographic Assay
	Species Reactivity	Human
	Type of Sample	Serum,Plasma
	Time to Result	≤ 30 minutes
	Ability to evaluate negative or positive test result	Yes
	Assay Sensitivity (%)	100%
	Assay Specificity (%)	≥98%
	Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature	Yes
	Contains an internal control dot/band for the confirmation that the test has been performed correctly	Yes
	The control dot/band able to detect the presence of human immunoglobulin and not be just a procedural control or meant merely for checking the flow of reagents or integrity of antigens except in lateral flow technology	Yes
	Maintenance of cold chain by the supplier during storage and transportation of Kits at 2°C to 8°C and placement of cumulative time temperature indicator technology on every pack of kits	Yes
KIT CONTENTS	Kit contents	Test Card/Cassette with Desiccant, Sample Dropper, Assay Buffer (if any)
	All the components shall be in the quantity as per pack size	Yes
	Adequate document detailing principle, components, methodologies, validity criteria, interpretation of results, performance characteristics, bio-safety, limitations of assay, storage condition, mfg & exp date and method of disposal provided with kit	Yes
	Positive and negative controls provided with each pack of kit	Yes
	Quantity of positive and negative controls provided	Sufficient for conducting 20% of the tests (10% negative and 10% positive controls)
PACKAGING	Pack size of kit	50 Tests
	The test kit packed in such a way that there is proivision to conduct single test at a time	Yes
	Each test card/cassette with desiccant individually packed in a hermetically sealed and non-permeable pouch	Yes
CERTIFICATIONS & REPORTS	Compliance to Medical Device Rules (MDR) 2017 as amended till date	Yes
	Availability of valid drug license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Valid Drug License Number	MFG/IVD/2023/000157
	Manufacturing unit certification	ISO:13485 (Latest)
	Additional voluntary certification available	CE
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission or along with supplies as per buyer requirement	Yes
SHELF LIFE	Shelf life in months from the date of manufacture	24 month
	Minimum shelf life of the product at the time of delivery to the consignee	3/4th of Total Shelf Life
ADVANCE SAMPLE	Agree to provide advance sample of the product for buyer's approval before commencement of supply in case of bidding	Yes
Additional Requirement	Additional Requirement	NA

Product Specification for Sunsure Salmonella Typhi IgM and IgG Antibodies Detection Rapid Test Kit

विनिर्देश|Specification	उप-विनिर्देश|Sub-Spec	मूल्य|Value
GENERAL FEATURES	Product Description	Typhoid Rapid Test Kit
	Clinical Purpose	To detect the presence of antibodies associated with Salmonella typhi in human blood samples
PRODUCT INFORMATION	Type of Kit	Salmonella Typhi IgM and IgG Antibodies Detection Rapid Test Kit
	Detection Type	Qualitative
	Testing Principle	Lateral Flow Immunochromatographic Assay
	Species Reactivity	Human
	Type of Sample	Whole Blood,Serum,Plasma
	Time to Result	≤ 30 minutes
	Ability to evaluate negative or positive test result	Yes
	Sensitivity	≥98%
	Specificity	≥98%
	Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature	Yes
	Contains an internal control dot/band for the confirmation that the test has been performed correctly	Yes
	The control dot/band able to detect the presence of human immunoglobulin and not be just a procedural control or meant merely for checking the flow of reagents or integrity of antigens except in lateral flow technology	Yes
	Maintenance of cold chain by the supplier during storage and transportation of Kits at 2°C to 8°C and placement of cumulative time temperature indicator technology on every pack of kits	Yes
KIT CONTENTS	Kit Contents	Test Card/Cassette with Desiccant, Sample Dropper, Assay Buffer (if any)
	All the components shall be in the quantity as per pack size	Yes
	Adequate document detailing principle, components, methodologies, validity criteria, interpretation of results, performance characteristics, bio-safety, limitations of assay, storage condition, mfg & exp date and method of disposal provided with kit	Yes
	Positive and negative controls provided with each pack of kit	Yes
	Quantity of positive and negative controls provided	Sufficient for conducting 20% of the tests (10% negative and 10% positive controls)
PACKAGING	Pack size of kit	50 Tests
	The test kit packed in such a way that there is proivision to conduct single test at a time	Yes
	Each test card/cassette with desiccant individually packed in a hermetically sealed and non-permeable pouch	Yes
CERTIFICATIONS & REPORTS	Compliance to Medical Device Rule (MDR) 2017 as amended till date	Yes
	Availability of valid drug license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Valid Drug License Number	MFG/IVD/2023/000157
	Manufacturing unit certification	ISO:13485 (Latest)
	Additional voluntary certification available	CE
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission or along with supplies as per buyer requirement	Yes
SHELF LIFE	Shelf life in months from the date of manufacture	24 month
	Minimum shelf life of the product at the time of delivery to the consignee	3/4 th of Total Shelf Life
ADVANCE SAMPLE	Agree to provide advance sample of the product for buyer's approval before commencement of supply in case of bidding	Yes
ADDITIONAL REQUIREMENT	Additional Requirement	NA

Product Specification for Sunsure Pregnancy Rapid Test Kit

विनिर्देश|Specification	उप-विनिर्देश|Sub-Spec	मूल्य|Value
GENERAL	Product Description	Pregnancy Rapid Test Kit
	Clinical purpose	To detect the presence of human chorionic gonadotropin (hCG) hormone in urine
PRODUCT INFORMATION	Detection Type	Qualitative
	Testing Principle	Single Step, self performing sandwiched immunoassay using colloidal gold and anti hCG antibodies in lateral flow immunochromatography format
	Specimen required for testing	Urine
	Ability to Evaluate Negative or Positive test result	Yes
	Sensitivity	≥25 milli I.U/ ml of urine
	Specificity	100% (no cross reactivity with other gonadotropin hormones like LH, FSH etc)
	Built-in control for confirmation that the test has been performed correctly	Yes
	Nitrocellulose paper coated with anti HCG antibodies for Test band and appropriate reagents for control band	Yes
	Kit stable at room temperature	Yes
	Maintenance of recommended temperature during storage and transportation of kit by the supplier	Yes
KIT CONTENTS	Main item in test kit for performing the test	Card/Cassette
	Material of Card/Cassette	ABS or PP
	Disposable dropper for urine specimen addition to be provided with each test pouch	Yes
	Every test pack should have moisture indicating silica gel pouch	Yes
	Packaging insert in English detailing the principle, components, methodologies, validity criteria, performance characteristics,bio-safety, limitations of assay, storage condition, manufacturing and expiry dates and methods of disposal to be provided	Yes
PACKAGING	Pack Size	50 Tests
	Each test kit should be indivdually packed in a moisture proof pouches	Yes
	Pouch specification	Triple layered laminated pouch having aluminium foil in the middle layer
	Packing	Laminated Printed cartons and the cartons packed in suitable corrugated shipper box for dispatch
CERTIFICATIONS & REPORTS	Compliance to Medical Device Rules (MDR) 2017 as amended till date	Yes
	Availability of valid medical device license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Valid Medical Device License Number	MFG/IVD/2023/000034
	Manufacturing unit certification	ISO:13485 (Latest)
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission or along with supplies as per buyer requirement	Yes
SHELF LIFE	Shelf life in months from the date of manufacture	24 month
	Minimum shelf life of the product at the time of delivery to the consignee	3/4th of Total Shelf Life
ADVANCE SAMPLE	Agree to provide advance sample of the product for buyer's approval before commencement of supply in case of bidding	Yes
ADDITIONAL REQUIREMENT	Additional Requirement	NA

ईपीबीजी विवरण | ePBG Detail

सलाहकार बैंक | Advisory Bank :	NA
ईपीबीजी प्रतिशत (%) | ePBG Percentage(%):	NA

नियम और शर्तें|Terms and Conditions

1. Special terms and conditions- Version:1 effective from 04-05-2023

1.1
1. All Provisions of Drugs and Cosmetics Act, 1940 and Rules (including Medical Device Rule 2017) made there under as amended till date will always be applicable. This will include all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
2. The sellers are registered on GeM based on self-declaration of valid Drug License, product certification, test reports etc. However, buyers must check and validate the details at their end for all applicable licenses and certifications e.g., validity and authenticity/genuineness of drug license, product certification, manufacturer certification/licenses, test reports etc.
3. In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products, including verifying the validity and authenticity of drug license held by them.
4. The price offered by the seller/bidder shall not, in any case exceed the DPCO/NPPA controlled price or price fixed by State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
5. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC/GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure items are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede General Terms and Conditions ("GTC"), whenever there are any conflicting provisions.

1.2 SPECIAL TERMS AND CONDITIONS (STC)

1. All Provisions of Drugs and Cosmetics Act, 1940 and Rules (including Medical Device Rule 2017) made there under as amended till date will always be applicable. This will include all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
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2. The sellers are registered on GeM based on the self declaration of valid Medical Device License, product certification, test reports etc. However, buyers must check and validate the details at their end for all applicable licenses and certifications e.g., validity and authenticity/genuineness of license, product certification,

manufacturer certification/licenses, test reports etc.

3. In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products, including verifying the validity and authenticity of license held by them.
4. The price offered by the seller/bidder shall not, in any case exceed the DPCO/NPPA controlled price or price fixed by State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
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2. General Terms and Conditions-

2.1 This contract is governed by the General Terms and Conditions, conditions stipulated to this Product/Service as provided in the Marketplace.

2.2 This Contract between the Seller and the Buyer, is for the supply of the Goods and/ or Services, detailed in the schedule above, in accordance with the General Terms and Conditions (GTC) unless otherwise superseded by Goods / Services specific Special Terms and Conditions (STC) and/ or BID/Reverse Auction Additional Terms and Conditions (ATC), as applicable

2.3 All GeM Sellers / Service Providers are mandated to ensure compliance with all the applicable laws / acts / rules including but not limited to all Labour Laws such as The Minimum Wages Act, 1948, The Payment of Wages Act, 1936, The Payment of Bonus Act, 1965, The Equal Remuneration Act, 1976, The Payment of Gratuity Act, 1972 etc. Any non-compliance will be treated as breach of contract and Buyer may take suitable actions as per GeM Contract.

3. Buyer Added Bid Specific Terms and Conditions-

3.1 *Scope of Supply*:
Scope of supply (Bid price to include all cost components) : Only supply of Goods

3.2 *Generic*:
OPTION CLAUSE: The Purchaser reserves the right to increase or decrease the quantity to be ordered up to 25 percent of bid quantity at the time of placement of contract. The purchaser also reserves the right to increase the ordered quantity by up to 25% of the contracted quantity during the currency of the contract at the contracted rates. Bidders are bound to accept the orders accordingly.

3.3 *Certificates*:
Bidder's offer is liable to be rejected if they don't upload any of the certificates / documents sought in the Bid document, ATC and Corrigendum if any.

3.4 *Generic*:
Shelf Life: The Product/Spare parts to be supplied as part of the services must have minimum

3/4
Shelf Life. On the date of supply, minimum
3/4
usable shelf life should be available / balance.

3.5 *Certificates*:
To be eligible for award of contract, Bidder / OEM must possess following Certificates / Test Reports on the date of bid opening (to be uploaded with bid):

The bidder should provide any one of these BIS/CE/FDA and ISO certification of the manufacturer.
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