

## अनुबंध | Contract



अनुबंध क्रमांक | Contract No: GEMC-511687783296259

अनुबंध तिथि | Generated Date : 28-Mar-2024

| संगठन विवरण   Organisation Details  | खरीदार विवरण   Buyer Details   |
|---|--|
| प्ररूप   Type : State Government<br>मंत्रालय   Ministry : -<br>विभाग   Department : Medical Education Department Uttar Pradesh<br>संगठन का नाम   Organisation Name : Directorate of Medical Education and Training<br>कार्यालय क्षेत्र   Office Zone : Director General Medical Education | पद   Designation : BUYER<br>संपर्क नंबर   Contact No. : -<br>ईमेल आईडी   Email ID : buyer62.dmet.up@gembuyer.in<br>जीएसटीआईएन   GSTIN : -<br>पता   Address : AUTONOMOUS STATE MEDICAL COLLEGE AMETHI, Raebareli, UTTAR PRADESH-229309, India |

| वित्तीय स्वीकृति विवरण   Financial Approval Detail   | भुगतान प्राधिकरण विवरण   Paying Authority Details  |
|--|--|
| आईएफडी सहमति   IFD Concurrence : Yes<br>प्रशासनिक अनुमोदन का पदनाम   Designation of Administrative Approval : Principal<br>वित्तीय अनुमोदन का पदनाम   Designation of Financial Approval : Finance Controller | Role: PAO<br>भुगतान का तरीका   Payment Mode: Offline<br>पद   Designation : PAO<br>ईमेल आईडी   Email ID : pao28.dmet.up@gembuyer.in<br>जीएसटीआईएन   GSTIN : -<br>पता   Address: AUTONOMOUS STATE MEDICAL COLLEGE AMETHI, Raebareli, UTTAR PRADESH-229309, India |

| विक्रेता विवरण   Seller Details  |
|--|
| जेम विक्रेता आईडी   GeM Seller ID : FTWL240010899150<br>कंपनी का नाम   Company Name : SHREE SHYAM TRADERS<br>संपर्क नंबर   Contact No. : 06392275562<br>ईमेल आईडी   Email ID : shreeshyamtraders142@gmail.com<br>पता   Address : 0,1,0,ward no 16 nagarwa,Katra Lal ganj Gauriganj, Amethi, UTTAR PRADESH-227409, -<br>एमएसएमई पंजीकरण संख्या   MSME Registration number : UDYAM-UP-05-0012543<br>एमएसई सामाजिक श्रेणी   MSE Social Category : General<br>एमएसई लिंग श्रेणी   MSE Gender : Male<br>जीएसटीआईएन   GSTIN: 09MQOPK7805B1ZF |

\*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 : xamin HCV Antibody and Antigen Detection Rapid Test Kit<br>ब्रांड   Brand : xamin<br>ब्रांड प्रकार   Brand Type : Registered Brand<br>कैटलॉग की स्थिति   Catalogue Status : OEM verified catalogue<br>कैसे बेचा जा रहा है   Selling As : OEM verified Reseller<br>श्रेणी का नाम और चतुर्थांश   Category Name & Quadrant : HCV Rapid Test Kits (Q2)<br>मॉडल   Model: HCV Rapid Test Device<br>एचएसएन कोड   HSN Code: HSN not specified by seller | 3,000                         | Test        | 100                                 | NA                                      | 300,000   |
| कुल ऑर्डर मूल्य   Total Order Value (in INR) |  |                               |             |                                     |   | 300,000   |

| परोक्षिती विवरण   Consignee Detail |  |   |                    |                   |   |  |
|------------------------------------|--|---|--------------------|-------------------|---|--|
| क्र.सं.   S.No                     | परोक्षिती   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 : BUYER<br>ईमेल आईडी   Email ID : buyer62.dmet.up@gembuyer.in<br>संपर्क   Contact : -<br>जीएसटीआईएन   GSTIN : -<br>पता   Address : AUTONOMOUS STATE MEDICAL COLLEGE AMETHI, | xamin HCV Antibody and Antigen Detection Rapid Test Kit | -                  | 3,000             | 28-Mar-2024   | 12-Apr-2024  |

## Product Specification for xamin HCV Antibody and Antigen Detection Rapid Test Kit

| विनिर्देश   Specification | उप-विनिर्देश   Sub-Spec   | मूल्य   Value   |
|---------------------------|---|---|
| GENERAL FEATURES          | Product Description   | HCV Rapid Test Kit  |
|                           | Clinical Purpose  | To provide diagnosis of Hepatitis C Virus infection                                 |
| PRODUCT INFORMATION       | Type of Kit   | HCV Antibody and Antigen Detection Rapid Test Kit                                   |
|                           | Generation  | 3rd Generation  |
|                           | Solid phase/particle coated with recombinant and / or synthetic peptide antigens for Core, NS3, NS 4, and NS5   | 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   | ≥95%  |
|                           | Declared sensitivity and specificity 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 provision 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/2021/000027   |
|                           | Manufacturing unit certification  | ISO:13485 (Latest)  |
|                           | Additional voluntary certification available  | FORM NO 28  |
|                           | 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  |

NA

## नियम और शर्तें | Terms and Conditions

### 1. Special terms and conditions- Version:2 effective from 19-05-2023

#### 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.

### 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

नोट: यह सिस्टम जनरेटेड फाइल है। कोई हस्ताक्षर की आवश्यकता नहीं है। इस दस्तावेज़ का प्रिंट आउट भुगतान/लेनदेन उद्देश्य के लिए मान्य नहीं है।

Note: This is system generated file. No signature is required. Print out of this document is not valid for payment/ transaction purpose.