KWAZULU-NATAL PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

ANNEXURE A: SPECIFICATION FORM

NAME OF PROCURING FACILITY	KING DINUZULU HOSPITAL COMPLEX MS4– NSI – 518/26-27
ITEM DESCRIPTION	Disposable, multi-parameter point-of-care diagnostic test cartridges (EDAN)
ITEM PURPOSE	The EDAN i15 BG10 test cartridges are single-use, disposable medical devices designed for point-of-care testing to rapidly measure blood gases, electrolytes, and metabolites from a micro-sample of whole blood

	ITEM DETAILED SPECIFICATION (INCLUDE SIZE, COLOUR, MATERIAL, ETC.)	COMPLIES (YES/NO)
1.	**General Item Overview** • **Item Description:** Disposable, multi-parameter point-of-care diagnostic test cartridges. • **Manufacturer / Brand:** EDAN Instruments, Inc. • **Model Designation:** BG10 Test Cartridges. • **Equipment Compatibility:** Exclusively for use with the EDAN i15 Blood Gas and Chemistry Analysis System. • **Procurement Quantity Required:** 4 x Boxes (Each box containing 100 test cartridges, totalling 400 individual cartridges).	
2.	**Functional & Technical Performance Specifications** • **Measured Parameters:** Single cartridge must simultaneously test and measure Blood Gases, Electrolytes, and Metabolites. • **Specific Analyte Panel:** Potential of Hydrogen (pH), Partial Pressure of Carbon Dioxide (pCO_2), Partial Pressure of Oxygen (pO_2), Sodium (Na^+), Potassium (K^+), Chloride (Cl^-), Ionised Calcium (Ca^{2+}), Glucose (Glu), Lactate (Lac), and Hematocrit (Hct). • **Technology:** Solid-state microfluidic biosensor and microchip liquid control technology. • **Sample Type Compatibility:** Whole blood (arterial, venous, or capillary). • **Sample Volume Capacity:** Micro-sample requirement between 60 µL to 140 µL max. • **Result Turnaround Time:** Less than 60 seconds from sample aspiration to data report. • **Calibration Protocol:** Fully automatic internal calibration embedded directly within each single-use cartridge; zero operator maintenance required. • **Contamination Control:** Strictly single-use, disposable design to prevent cross-contamination	
3.	**Storage, Packaging & Handling** • **Cartridge Storage Temperature:** Standard room temperature	

SPECIFICATION APPROVED BY

Name of End-user (in full)	F.N. KHUZWAYO	Name of SCM Rep (in full)	S. DOOKEN
Designation / Rank (in full)	Operational Manager	Designation/ Rank (in full)	Supply Chain - Demand
Signature		Signature	
Date	2026.09.08	Date	2026.09.08
e-mail			

Bidder Initial here: _____

RE:

	stability or refrigeration range between 2°C and 30°C. • **Packaging Integrity:** Every individual cartridge must be supplied hermetically sealed in protective foil pouches with active desiccant. • **Traceability:** Each individual pouch and external carton box must display clear batch numbers, manufacturing dates, and expiration dates. • **Minimum Shelf Life:** Cartridges must have at least 6 to 9 months of active shelf life remaining upon delivery to the facility	
4.	**South African National Compliance Requirements** • **Regulatory Licensing:** The local supplier must hold a valid Medical Device Establishment Licence issued by the South African Health Products Regulatory Authority (SAHPRA). • **National Tendering Prerequisite:** The bidding entity must attach proof of its SAHPRA licensing status to remain legally compliant and eligible for public and private healthcare procurement in South Africa. • **Quality Standards:** Devices must comply with International Quality Standards, holding verified **CE Certification (under IVDR Class C)** or equivalent international ISO 13485 standards for in vitro diagnostic medical devices. • **Traceability Integration:** Cartridges must feature functional barcode or QR code structures fully readable by SAHPRA-compliant local hospital information systems (HIS) or point-of-care data management systems	

UNIT OF MEASURE OR PACKAGING I.E. (UNIT/BOX/ROLL/PACK/BAIL ETC)	BOX **(Total of 04 boxes requested)**
SAMPLE REQUIRED (YES/NO) IF YES WHEN AND HOW?	YES **Sample OR Detailed Brochure (NOT PICTURE) must be submitted with quote**
ADDENDUM TO SPECIFICATION ATTACHED (YES OR NO)	NO

Note:

1.
2.
3.

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STANDARD QUOTATION DOCUMENT FOR QUOTATIONS UP TO R1 000 000

OFFICIAL PRICE PAGE FOR QUOTATIONS UP TO R1 000 000

QUOTE NUMBER: ZNQ / KDH / 378 / 26 / 27

DESCRIPTION: DISPOSABLE EDAN TEST CARTIDGES

THE BELOW PREFERENCE POINTS WILL BE ALLOCATED IN COMPLIANCE WITH THE DEPARTMENTAL PREFERENCE PROCUREMENT POLICY (KNOWN AS SCM PPP):	POINTS ALLOCATED
RDP Goal: Full points allocated to promote South African owned enterprises	20

ICN NUMBER	QUANTITY	UNIT OF MEASURE	DESCRIPTION	BRAND & MODEL	COUNTRY OF MANUFACTURE	PRICE R	PRICE C
	04	BOX	DISPOSABLE EDAN TEST CARTRIGDES				
			PLEASE PROVIDE SAMPLE ON OR				
			BEFORE CLOSING DATE, FAILING				
			WHICH WILL BE DISQUALIFIED				
			SPECIFICATION ATTACHED				
			SEE ATTACHED EVALUATION CRITERIA				
			WITH REQUIRED RETURNABLE				
			DOCUMENTS, COMPLETE & INITIAL				
			CSD COMPLIANT /				
			ATTACH ORIGINAL / CURRENTLY				
			CERTIFIED BEE CERTIFICATE				
VALUE ADDED TAX @ 15% (Only if VAT Vendor)							
TOTAL QUOTATION PRICE (VALIDITY PERIOD 90 Days)							

DOES THIS OFFER COMPLY WITH THE SPECIFICATION? YES / NO

IS THE PRICE FIRM? YES / NO

DOES THE ARTICLE CONFORM TO THE S.A.N.S. / S.A.B.S. SPECIFICATION? YES / NO

STATE DELIVERY PERIOD (E.G. 3 DAYS, 1 WEEK) _____

NAME OF BIDDER: _____ SIGNATURE OF BIDDER: _____

[By signing this document, I hereby agree to all terms and conditions]

CAPACITY UNDER WHICH THIS QUOTE IS SIGNED: _____ DATE: _____