

RFQ1940102 – 26/27– CLARIFICATION QUESTIONS AND RESPONSES

TITLE	FOR THE APPOINTMENT OF A PANEL OF SERVICE PROVIDERS FOR ISO 13485: 2016 CERTIFICATION FOR NHLS FOR A PERIOD OF FIVE (5) YEARS
DATE	01 October 2026

QUESTION NO	Clarification Questions	Response
1	IFC Global LLC is accredited by United Accreditation Foundation (UAF) under ISO/IEC 17021-1, with ISO 13485:2016 explicitly included in our current accreditation schedule. Please confirm that this is acceptable under the requirement for SANAS or another accreditation body that is a signatory to the applicable IAF MLA.	Yes, this is acceptable.
2	Annexure B includes a “Gap Assessment Audit.” Please confirm that this is intended as a non-consulting certification-related assessment and does not require the certification body to design, implement, or recommend solutions for the management system.	No, this is a certification audit, Gap assessment was removed.

3	3. IFC Global LLC is a U.S. company with no South African registered entity, branch, permanent establishment, South African-source income, or South African tax liability. Please confirm which CSD and SARS/TCS fields or documents should be marked not applicable for a foreign bidder in this position.	A foreign bidder that is not registered for tax in South Africa and has no South African tax liability may indicate the relevant SARS Tax Compliance Status, income tax and VAT-related fields as 'Not Applicable'. Where a TCS Pin or South African tax reference number is requested, the bidder should provide a signed declaration confirming its foreign status and that it is not liable for tax registration in South Africa. The bidder must, however, ensure that its CSD registration is completed as a foreign supplier and that all other applicable bid requirements are complied with.
4.	Please confirm how a foreign bidder that is not registered for South African VAT should complete the VAT fields and the instruction to quote all prices in South African Rand inclusive of VAT.	For a foreign bidder that is not a South African VAT vendor, the bid price must be quoted in South African Rand (ZAR) and must represent the final price payable by the institution, inclusive of any taxes applicable to the bidder. As South African VAT is not applicable to the bidder, the VAT component is reflected as nil (R0.00).
5	For the ISO 13485 and IVD/medical-device experience criteria, will client reference letters and redacted certification project records be accepted where complete audit reports are confidential?	Yes, this may be accepted
6	Is there a maximum email or attachment size, required file format, required subject line, or procedure for splitting the submission across more than one email?	Up to 5MB, you may split across more than 1 email.

7	Are any remote or hybrid audit activities permitted, and are indicative dates available for the four facilities listed in Annexure B?	No, preferably physical audits, dates will can be made available by the facilities soon as appointments have been done.
8	Confirm whether a foreign supplier answering No to all five SBD1 foreign-supplier questions should show VAT as zero and omit a SARS PIN; and	Where a bidder is a foreign entity with no South African tax registration or tax liability, the bidder may indicate the SARS Tax Compliance Status (TCS) PIN requirement as " Not Applicable " and provide supporting confirmation of its foreign status. Where the bidder is not registered for South African VAT and is not required to charge VAT in South Africa, the VAT amount may be reflected as 0% or " Not Applicable ", provided that the pricing schedule clearly indicates that no South African VAT has been included in the quoted price. All submissions will remain subject to verification and evaluation in accordance with the bid requirements and applicable legislation.
9	Confirm whether electronically signed official forms and non-South-African witnesses are acceptable for the emailed bid.	It is acceptable