TCC/2026/05/0003/114436/RFP CLARIFICATIONS

No.	Date received	Date responded	Clarification Question	Response Transnet
1	6/24/2026	6/24/2026	**Exclusive Distributor, Joint Venture and ISO Certificates:** If a South African bidder is the appointed exclusive distributor of an overseas manufacturer, or forms a Joint Venture (JV) with that manufacturer, will Transnet accept the manufacturer's ISO 9001 and ISO 13485 certificates for purposes of this tender? If yes, what supporting documents must be submitted with the bid (e.g. distributor agreement, manufacturer authorisation letter, or JV agreement)?	Yes. Transnet may consider the ISO 9001 and/or ISO 13485 certifications of an overseas manufacturer where the bidder demonstrates an authorised commercial relationship with the manufacturer and provides the required supporting documentation. The bidder remains fully responsible for contract performance, product quality, supply continuity, logistics, and compliance with all tender requirements. The following supporting documentation must be provided, where applicable: For an Exclusive Distributor Arrangement: I. A valid manufacturer authorisation letter appointing the bidder as an authorised distributor, reseller, or representative; II. A distributor agreement, agency agreement, or equivalent documentary proof of the relationship; III. Copies of the manufacturer's valid ISO 9001 and/or ISO 13485 certificates; IV. Confirmation that the products offered under this tender are manufactured under the certified quality management system. For a Joint Venture (JV): I. A signed Joint Venture Agreement identifying the parties and their respective responsibilities; II. The JV must be constituted in accordance with the tender requirements and clearly identify the lead partner and responsibilities of each party; III. Copies of the manufacturer's valid ISO 9001 and/or ISO 13485 certificates; IV. Confirmation that the products offered under this tender will be sourced, manufactured, or supplied through the certified entity. Transnet reserves the right to verify the authenticity and validity of all certificates and supporting documentation submitted. For avoidance of doubt, reliance on a manufacturer's certification does not transfer contractual responsibility from the bidder to the manufacturer or JV partner.
			Purchase Order Funding Facility: Annexure K allows bidders to provide an overdraft facility as proof of financial capacity. Will Transnet accept a letter from a recognised purchase order funding institution confirming an approved funding facility available to the bidder for government contracts, instead of a bank overdraft facility? This is generally acceptable across other SOEs as part of financial supporting confirmation to ensure that tenders are fulfilled. If yes, what information must be included in the funding confirmation letter?	Transnet may consider funding confirmation letters from recognised funding institutions as supplementary evidence of financial capacity, provided that the documentation demonstrates access to funding equivalent to or exceeding the minimum financial capacity requirements of the tender. The funding arrangement must demonstrate the bidder's ability to procure, hold, and deliver the required goods throughout the contract period. The funding institution must be a legally registered financial services provider or recognised commercial funding institution. The funding confirmation letter must be issued on the institution's official letterhead and include, at a minimum: I. The name and registration number of the funding institution; II. The bidder's legal name and registration number; III. Confirmation that the bidder has been assessed and approved for funding; IV. The approved funding limit or facility value available to the bidder; V. Confirmation that the funding facility may be utilised for the procurement, supply, and delivery of goods under government, state-owned entity, or similar contracts; VI. The validity period of the funding approval; VII. Contact details of an authorised representative of the funding institution; VIII. Signature of an authorised representative of the funding institution. Transnet reserves the right to verify the authenticity and validity of the funding confirmation directly with the issuing institution and may request additional supporting information where required. For evaluation purposes, the approved funding facility value must be equal to or greater than the minimum financial capacity requirement specified in the tender documentation. For avoidance of doubt, the existence of a funding facility does not transfer contractual obligations. The bidder remains fully responsible for the successful execution of the contract and compliance with all tender requirements.
			SAHPRA and International Regulatory Approvals: The functionality criteria allocate points for SAHPRA accreditation. Considering that many ophthalmic products and spectacle frames are manufactured outside South Africa and may already hold approvals or certifications from recognised international regulatory authorities such as the US FDA, CE Marking (European Union), MHRA (United Kingdom) or other equivalent authorities, please clarify: 1.Will Transnet recognise such international regulatory approvals as evidence of product quality, safety and regulatory compliance where SAHPRA registration is not legally required for the specific product category? 2.Where a bidder is an authorised South African distributor of an internationally approved manufacturer, will the manufacturer's international regulatory approvals and certifications be considered during evaluation?	1.Yes. Where SAHPRA registration, licensing, or accreditation is not legally required for a specific product category, Transnet may consider internationally recognised regulatory approvals and certifications as supporting evidence of product quality, safety, and regulatory compliance. Examples of acceptable supporting evidence may include: I. CE Marking (European Union); II. United States Food and Drug Administration (FDA) approvals or registrations; III. Medicines and Healthcare products Regulatory Agency (MHRA) approvals or registrations (United Kingdom); IV. ISO 13485 certification relating to the manufacture of medical devices; V. Other recognised international regulatory approvals or quality certifications applicable to the product category. 2.Yes. Where a bidder is an authorised South African distributor, reseller, or representative of an internationally approved manufacturer, the manufacturer's regulatory approvals, certifications, and quality management credentials may be submitted and will be considered during evaluation, provided that the bidder submits documentary evidence demonstrating the relationship with the manufacturer. Such evidence may include: I. Manufacturer authorisation letters; II. Distributor or agency agreements; III. Exclusive distribution agreements; or IV. Other documentary proof acceptable to Transnet. Bidders should note that certain products included in this tender may not require SAHPRA registration under current South African regulatory requirements. In such instances, bidders are encouraged to submit relevant manufacturer certifications, international regulatory approvals, technical datasheets, and product specifications to demonstrate product quality and compliance. For avoidance of doubt, where SAHPRA compliance is legally required for a specific product category, bidders must still demonstrate compliance with applicable South African regulatory requirements. International approvals will be considered as supplementary evidence and will not replace mandatory South African regulatory requirements where such requirements apply. For purposes of the Quality Assurance evaluation criterion, internationally recognised regulatory approvals and certifications may be submitted as supporting evidence of product quality, safety, and regulatory compliance where SAHPRA registration is not applicable to the specific product category. Such evidence will be considered together with all other information submitted by the bidder during evaluation.
2	6/25/2026	6/29/2026	We specialise in medical equipment and we have been supplying the Department of Health for a number of years. We are also SAHPRA certified but we see that you placed an ISO requirement in all three of the above mentioned bids which will eliminate small black companies from bidding. This seems to be unfair as it's only for supply unless you're requesting ISO certificate of the potential manufacturer which we will be purchasing from. We humbly request that you provide us with further clarity and be lenient towards emerging black companies.	Please note that the ISO 9001 and/or ISO 13485 requirements relate to the manufacturer of the medical devices and equipment being offered, and not necessarily to the bidding entity where it is acting as an authorised distributor or reseller. Accordingly, where a bidder is supplying products manufactured by a third-party manufacturer, Transnet will accept the manufacturer's ISO certificates, provided the bidder submits supporting documentation demonstrating its authority to supply those products. Such supporting documentation may include, but is not limited to: I. A valid manufacturer authorisation letter; II. An exclusive distributor agreement; III. A reseller or distribution agreement; or IV. Any other documentary evidence confirming the bidder's authority to market and supply the manufacturer's products. The bidder remains responsible for ensuring that all products offered comply with the technical specifications and all other mandatory requirements of the tender, including applicable SAHPRA requirements where relevant.