PUBLIC CONTRACTS REVIEW BOARD

Case No. 730

CT 2123/2013: Tender for the Supply of Coagulant Reagents with Equipment on Loan.

The tender was published on the 10th December 2013. The closing date was the 4th February 2014. The estimated value of the Tender was €1,492,295.

On the 4th July 2014 Cherubino Limited filed a letter of objection objecting to the disqualification of their tender.

Three (3) bidders had participated in this tender.

The Public Contracts Review Board composed of Dr Anthony Cassar (Chairman), Dr Charles Cassar and Mr Lawrence Ancilleri as members convened a hearing on Tuesday the 2nd September 2014 to discuss the objection.

Present for the hearing were:

Cherubino Limited - Appellant

Dr David Basile Cherubino	Representative
Dr Matthew Paris	Legal Representative

Technoline Limited - Preferred Bidder

Mr Chris Rizzo	Representative
Mr Ivan Vassallo	Representative
Dr Paul Gonzi	Legal Representative

Central Procurement & Supplies Unit - Contracting Authority

Ms Connie Miceli	Chairperson Evaluation Board
Dr James Camilleri	Member Evaluation Board
Mr Alexander Gatt	Member Evaluation Board
Ms Agnes Saunders	Member Evaluation Board
Ms Alicia Vella Letteridge	Representative

Department of Contracts

Mr Nicholas Aquilina	Procurement Manager

The Chairman made a brief introduction and invited appellant's representative to make his submissions.

Dr Matthew Paris on behalf of the appellant referred to the letter of rejection of appellant's bid where it was informed that its tender had not been successful since *"The provided literature for the Von Willebrand RiCof Factor shows that it is not CE marked."* He asserted that this was not true since when going through appellant's tender it clearly stated at 1.2 that: *"The reagents and other consumables offered are of proven accuracy and precision. A detailed protocol for each type of reagent is submitted with the offer. All reagents and kits offered are CE approved..."* With this, appellant firm Cherubino Limited clearly confirmed that what was requested, that is that reagents and kits be CE approved, was in fact offered. Thus it is assumed that the rejection of the bid was through an error.

Mr Alexander Gatt, ID No. 152974M Specialist in Haematology, on behalf of the contracting authority under oath, replying to questions by the Chairman explained said that since about two years ago the hospital started giving this service to patients who although needing to undergo operations, had thin blood that was difficult to coagulate. The patients are given replacement injections and the progress is monitored in real time with this test before undergoing operations. Previously these patients had to be sent overseas. Thus this service is crucial for these patients who have to be operated. The test products are normally marked with the CE certification. All the parts of the test as well as the procedure should be CE marked. The whole process, test being procured must be validated and not just the parts have to bear the CE mark. This affords us the peace of mind that it is safe 100% for the patients.

However whereas all the other tests offered by appellant bear the CE mark, the protocol in question states *that "This protocol is suggested by Dragnostica Stago to assist users who choose to utilize the above mentioned reagents and instrument. Users assume total responsibility for validation of test results obtained with this protocol so as to be in full compliance with current local regulations applicable to in vitro reagents. Under no circumstances, shall Diagnostica Stago be held liable for any consequential damages resulting from the use of this protocol."* Mr Gatt continued that he could not professionally accept this. Replying to questions by Dr Matthew Paris, witness continued that the reagents appellant submitted were Siemens while the equipment was Stago. He confirmed that the appellant did not state that the product was not CE approved. The document submitted by appellant did not state that it was not CE approved but contained the above disclaimer. It was on this basis that the evaluation board concluded that the product was not CE marked. All established protocols are validated by the CE mark.

Dr Matthew Paris on behalf of the appellant insisted that nowhere in the tender document does it specify that a submission of CE mark was mandatory. Appellant had confirmed in provision 1.2 that everything submitted was CE approved. Appellant had satisfied the mandatory requirements. The contracting authority, if it had doubts, could have asked for clarifications. He filed a certificate from Siemens that shows its product was CE approved. He reiterated that a clarification should have been sought.

Ms Connie Miceli on behalf of the contracting authority remarked that the tender specifications said "the reagents and other consumables which are offered must be of proven accuracy and precision. A detailed protocol for each kit or each type of reagent must be submitted with offer. All reagents and kits must be CE approved and material safety data sheets are to be submitted for each reagent/kit." The tender did not allow any clarifications regarding the technical specifications.

Dr Matthew Paris spoke about the literature required by the tender document that was

mandatory. Clause 1.1, said "literature including code numbers and description of items." There was no mention of providing CE certifications. He insisted that his client never indicated that the offered product was not CE approved. Thus the decision to reject the bid should be revoked because what the letter of rejection stated was not true. His client had confirmed that his product was CE marked.

Dr Paul Gonzi on behalf of the preferred bidder said that clause 1.2 stated clearly that all reagents and kits must be CE approved. The CE marking is a requirement from the EC for medical devices and equipment. Furthermore clause 12.3 of the tender states that "all offers must include detailed information in reply to the specifications stated above". Appellant had to submit a product with certain specifications that included detailed information. Appellant failed to do so. The evaluation board could not have just relied on a bidder's declaration that its product complied. The decision of the European Court of Justice, cited in the letter of objection, Commission vs Denmark was not as quoted in the letter but it states "It must be stated first of all that the observance of the principle of equal treatment of tenderers requires that all tenderers comply with the tender conditions so as to ensure an objective comparison of the submitted tenders." This is in fact the opposite of what the appellant stated about the decision.

At this point the hearing was closed.

This Board,

Having noted appellant's objection, in terms of the "Reasoned Letter of Objection" dated 2nd July 2014 and also through appellant's verbal submissions during the hearing held on 2nd September 2014, had objected to the decision taken by the pertinent authority, in that:

a) **Appellant Company contends that its offer was unfairly discarded on the alleged reason given by the Contracting Authority, that appellant's products were not CE approved. In this regard, appellant contends that the declaration given by same assured in itself the fact that the latter would supply the products CE approved as requested in the Tender Document, in accordance with Provision 1.2;**

b) **Appellant claims that, if the Contracting Authority had any doubts about the CE approval, the latter should have requested clarifications;**

Having considered the Contracting Authority's verbal submissions during the hearing held on 2nd September 2014 in that:

a) **The Technical Expert on the Evaluation Board explained very vividly, under oath, the procedure in applying this product on patients. The prime decisive factor on which the Evaluation Board's decision rested was "to choose the most reliable and safe product for the benefit of the patients' safety". The product had to be CE approved. However from the Literature submitted by the appellant company, it was not possible for the Evaluation Board, to determine whether the product offered by appellant was CE approved;**

b) **One of the main concerns of the Evaluation Board was the Disclaimer made by the Supplier of the Appellant's product. The Contracting Authority chose the safest product which was CE approved.**

Reached the following conclusions:

1. **With regards to the first contention of the appellant company, in that its product was CE approved, and following the Technical Expert's submission (under oath), this Board acknowledges the importance of choosing the safest product to be administered on patients. One of the assurances which the Tender Document stipulated was that all reagents and Kits had to be CE approved and material safety Data sheets were to be submitted for each Reagent/Kit. From the Technical Literature submitted by the appellant, the Evaluation Board, could not determine whether appellant's products were CE approved;**

   The fact that the Appellant Company submitted the declaration that all products being offered by appellant were CE approved does not show evidence, (from literature submitted by the same), that the products were in actual fact CE approved.

   This Board also noted the fact that the appellant's product supplier submitted a disclaimer:

   "Users assume total responsibility for validation of test results obtained with this protocol so as to be in full compliance with current local regulations applicable to in vitro reagents. Under no circumstances, shall the supplier be held liable for any consequential damages resulting from the use of this protocol"

   This same Board opines that this disclaimer submitted by the supplier of the appellant's product does not augur favourably when one considers and establishes the fact that the Patient's Health and Safety is of the utmost and determing importance in the Evaluation Process. In this regard, this Board upholds the Contracting Authority's decision to select the safest product for the benefit of the Patient's safety.

2. **With regards to the Second Contention of the Appellant Company, in that the Evaluation Board could have asked for clarifications; this Board opines that the tender in fact, did not allow any clarifications regarding the Technical Specifications. This Board upholds this mandatory condition laid out in the Tender Document.**

In view of the above, this Board finds against the Appellant Company and recommends that the deposit paid by appellant should not be reimbursed.

Dr Anthony Cassar	Dr Charles Cassar	Mr Lawrence Ancillieri
Chairman	Member	Member

6 October 2014