

PUBLIC CONTRACTS REVIEW BOARD

Case No. 921

CFT 10384/2015

Tender for Supply of Implantable Dual Chamber Defibrillator Without Leads (Lot 1).

The Tender was published on the 11th September 2015. The closing date was on the 12th October 2015. The estimated value of the Tender is €120,000.00 (Exclusive of Vat).

On the 22nd February 2016 Technoline Limited filed an objection against the decision of the Contracting Authority to award the Tender to VJ Salomone.

The Public Contracts Review Board composed of Dr Anthony Cassar (Chairman), Dr Charles Cassar and Mr Lawrence Ancilleri as members convened a hearing on Thursday the 7th April 2016 to discuss the objection.

Present for the hearing were:

Technoline Limited:

Mr Ivan Vassallo	Sales & Marketing Manager
Mr Craig Doermann	Marketing
Ms Damaris Lofaro	Sales Executive
Dr Paul Gonzi	Legal Representative

VJ Salomone:

Mr Chris Treeby Ward	Representative
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Central Procurement and Supplies Unit:

Ms Doreen Gouder	Secretary Evaluation Board
Dr Mark Sammut	Member Evaluation Board
Mr Frankie Caruana	Member Evaluation Board
Ms Marika Cutajar	Representative
Dr Stefan Zrinzo Azzopardi	Legal Representative

Dr Paul Gonzi on behalf of the Appellant firm explained and pointed out that since most points in this objection, with the exception of one, were the same as those raised in the Letter of Objection against the award of Tender CFT 019/10381/15 Implantable Cardiac Resynchronization Therapy Defibrillator CRT-D Without Leads heard earlier (Case 920), he would make reference to the evidence submitted in that case in order to avoid unnecessary repetition of submissions. The point which differed from the other case was about item 17 at page 19 of the Tender Document which states that “*remote monitoring system including all accessories and life-long use of service.*” Dr Gonzi contended that the Recommended Bidder may not have submitted this. He asked whether this item had been submitted by the Recommended Bidder or not.

Dr Stefan Zrinzo Azzopardi on behalf of the Contracting Authority objected to the production of evidence on this item since it was not part of the original objection. He submitted that this issue being raised was not indicated in the original Letter of Objection and neither was it part of the same detailed Letter.

Dr Paul Gonzi for the Appellant contended that the Letter of Objection had claimed that the Recommended Bidder was “*not technically compliant*” and this included this item. He contended that the Contracting Authority had enough time during the present hearing to give a reply on this point. Dr Gonzi also pointed out that a person who had been part of the adjudication board was the same person who had prepared the Tender. The Appellant had not seen the need to ask for any clarifications regarding the use of the word “automatic” since they understood that automatic meant just that on its own.

Dr Stefan Zrinzo Azzopardi for the Contracting Authority said that there was no need to recapitulate on the Technical Specifications. He insisted that bidders had other methods open to them in case of anything not being clear before the adjudication process. This Board had to see whether the submissions of the parties were within the parameters or not.

At this point the hearing was closed.

This Board,

Having noted the Appellant’s Objection in terms of the “*Reasoned Letter of Objection*” dated 2 March 2016 and also through their verbal submissions during the Public Hearing held on 7 April 2016 had objected to the decision taken by the Pertinent Authority, in that:

a) The Appellant Company contends that the Recommended Bidder’s

offer should have been deemed to be non-compliant on specifications Four (4), Eight (8), Nine (9) and Eleven (11). In this Regard the Appellant maintains that his offer did satisfy the Technical Specifications as follows:

(i) Specification No 9

The Appellant contends that the Recommended Device does not have the “*Availability of Atrial Antitachycardio pacing algorithms*”, so that their offer is not Technically Compliant, in this regard. In fact, the device offered by the Recommended Bidder was only suitable for “*Ventricular Arrhythmias*”, ie for the lower chamber of the heart.

In this respect, the Appellant Company contends that the Preferred Device could only be corrected or adjusted to the patient’s requirement in a clinic or hospital and not performed automatically whilst the Appellant’s device can be set and adjusted automatically outside a clinic or hospital.

(ii) **Specifications Nos 4 and 8**

Technoline Ltd are contending that the Preferred Device is not able to optimize output as confirmed by the product manual. At the same instance, the Tender Specifications requested that for the device to be adjusted there will be no need for the patient to be re-hospitalized. After all, the purpose of this type of pacemaker was to enable the patient to live a normal life without having to attend hospital for any adjustment/setting. In this respect, the Preferred Device cannot satisfy this requirement.

(iii) **Specification No 11**

This specification requested the “*Availability of Algorithms to minimise ventricular pacing in the event of a satisfactory intrinsic rhythm.*” In this regard, the device offered by VJ Salomone Pharma Ltd does not meet these specifications. On the other hand, the device offered by Technoline Ltd adjusts the heart rate automatically, thus reducing the needs to attend a clinic/hospital.

At the same instance, the Appellant Company refers to Clause 21.4 of the Tender Document wherein “*Clinical Evidence*” was

requested by the Contracting Authority to demonstrate and prove the accuracy of the device being offered.

In this regard, the Appellant did submit this required documentation whilst the device submitted by VJ Salomone Pharma Ltd did not have “*Clinical Evidence*”, to substantiate its accuracy.

b) The Appellant Company contends that Item 17 on Page 19 of the Tender Document dictated “*A remote monitoring system, including all accessories and life-long use of service.*” In this regard, Technoline Ltd maintain that the Recommended Bidder’s offer did not conform with this technical condition;

c) The Appellant also contends that one of the Evaluation Board members had also prepared the Tender Document.

Having considered the Contracting Authority’s verbal submissions during the Public Hearing held on 7 April 2016 in that:

a) **Specification 9**

The Contracting Authority maintains that the above mentioned Specification requested the availability of an “*Antitachycardia Mechanism*”. Nowhere, in the Tender Specifications was mentioned that this should be performed automatically.

The Contracting Authority rebuts the fact that the Preferred Device would require clinic attendance. Any necessary adjustments can be performed within five minutes and present no hazard to the patient’s health.

b) **Specifications 4 and 8**

The Contracting Authority through experience preferred applying the “*Antitachycardia Mechanism*” manually as the procedure has proved to be better carried out this way, rather than carry the procedure automatically.

c) **Specification 11**

The Contracting Authority is convinced that the chosen device is

according to the Technical Specifications as requested in the Tender Document.

- d) The Contracting Authority insists that since the Appellant's First Grievance was not even mentioned in their "*Reasoned Letter of Objection*", the contention raised by Technoline Ltd should be discarded;

- e) The Contracting Authority maintains that the Appellants had other alternative measures to raise their complaint.

Reached the following conclusions:

First and foremost, this Board would justifiably state that it's following decisions which are mostly based on the submissions made during the Public Hearing by medical experts. This Board also acknowledges the fact that the Technical Expert is an experienced consultant cardiologist specialising in "*Electro Physiology*" apart from being the end user of this Specialised device, (the pace maker).

Secondly, it is not this Board's competence to delve into the Technical Merits of the submissions made by both the Appellant Company and the Contracting Authority but rather to adjudicate the Evaluation Process of

this Particular Tender and in this regard, this Same Board would like to consider the following points:

1. Tender Specifications

From the submissions made by the Appellant Company, it has been clearly established that the word “*Automatically*” had been wrongly referred to by the Appellant. During the Technical Submissions it was vividly pointed out that the Tender Document nowhere implied or mentioned that the device should in all respects act automatically.

The word automatically was only used for “*Ventricular Tachycardia*” and “*Fibrillation*” and not for “*Atrial*”. The latter does not need an automatic function.

This Board justifiably notes that the Technical Specifications of this Tender did not, in any way, request an “*Automatic Atrial Antitachycardia Pacing*”. In this regard, this Board opines that the Appellant Company had all the remedial opportunity to ask for clarifications within the stipulated period, to clear any misunderstandings of any Technical Specification with the Contracting Authority.

In this respect, this Board justifiably points out that all the Technical Medical Jargon difficulties, if any, could have been clarified and Technoline Ltd did not avail itself of this remedial action.

2. Evaluation Process

This Board is credibly convinced that the Preferred Device is within the dictated Technical Specifications of the Tender. From the submissions made by the Consultant Cardiologist, this Board is comforted by the fact that the latter, who will be the end user, has credibly established as to why there was no need for a “Fully Automatic” device.

This Board also noted that the Preferred Device, which would carry out the necessary functions as stipulated in the Tender Document, was cheaper than that offered by the Appellant Company. In this regard, the Evaluation Process was carried out in a transparent and just manner.

3. With regards to the Appellant’s penultimate grievance, this Board justifiably notes that Technoline Ltd’s contention was not mentioned, or indicated, in their “Reasoned Letter of Objection”, dated 2 March 2016 and this Board credibly opines that it cannot enter into the merits of an objection on a particular item of the Tender Document,

if this was not referred in the “*Reasoned Letter of Objection*”.

This cardinal principle must be maintained as otherwise it will go against the principles of the Public Procurement Regulations for the Public Contracts Review Board to delve into the merits of a particular grievance which was not even mentioned by the Appellant Company. In this regard, this Board does not uphold the Appellant’s Penultimate Grievance.

- 4. With regards to the Appellant’s Final Grievance, this Board would like to credibly point out that this Procurement is of a highly specialised medical nature. This Board is comforted by the fact that in Malta, we have a limited number of specialists so that when a Tender of such a nature is to be issued, the assistance of these limited specialists is sought.**

In this particular case, the specialists chosen to dictate the Technical Medical Specifications are the same “*End Users*” so that this Board acknowledges the fact that the latter are fully aware of the requirement of this procurement.

This Board justifiably finds no “*Conflict of Interest*” or any

advantage given to any specific bidders. The Contracting Authority dictated the Technical Specifications in accordance to its specific requirements. In this regard, this Board does not uphold the Appellant's Final Contention.

- 5. On a general note, this Board credibly contends that the Grievance raised in this particular case could have been clarified, prior to the Evaluation Process.**

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

Dr Anthony Cassar
Chairman

Dr Charles Cassar
Member

Mr Lawrence Ancilleri
Member

19 April 2016