Case 1269 – CFT 020-0549/18 – Supply of Transthoracic Disposable External Pacing Electrodes

The publication date of the call for tenders was the 18th May 2018 whilst the closing date of the call for tenders was 8th June 2018. The estimated value of the tender (exclusive of VAT) was € 54,468.96

On the 14th January 2019 Cherubino Ltd filed an appeal against the Central Procurement and Supplies Unit (CPSU) as the Contracting Authority objecting that their bid was found not to be technically compliant. A deposit of € 400 was paid.

There were five (5) bidders.

On 26th February 2019 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Carmel Esposito as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellants – Cherubino Ltd

Dr Victor Axiak	Legal Representative
Mr Francis Cherubino	Representative
Mr Paul Calleja	Representative
Mr David Cherubino	Representative

Recommended Bidder – Krypton Chemists Ltd

Mr Matthew Arrigo	Representative

Contracting Authority – Central Procurement and Supplies Unit (CPSU)

Dr Marco Woods	Legal Representative
Ms Marika Cutajar	Chairperson Evaluation Committee
Ms Josette Camilleri	Secretary Evaluation Committee
Mr Edmond Balzan	Member Evaluation Committee

Dr Anthony Cassar Chairman of the Public Contracts Review Board welcomed the parties and invited them to make their submissions.

Dr Victor Axiak Legal Representative of Cherubino Ltd stated that the rejection of his clients' offer was a cause for concern, as the product they offered was used in 60 countries and held in the highest consideration. It efficacy was conformity certified by an independent laboratory and it was a tried and tested product with an attestation of equivalence when compared to similar

products. The Contracting Authority found fault with product at 70 joules meter readings and at 360 joules readings, and according to their tests the product burnt out after five uses. The Authority was claiming that the product was not fit for purpose when independent certification gave it a high commendation. They wished to hear the evidence of the person who tested the product and a record of the calibration tests of the equipment used in the test.

Engineer Chris Attard Montalto (260561M) called as a witness by the Board testified on oath that he is the Chief Biomedical Engineer at Mater Dei Hospital (MDH). His involvement was as the head of the department whilst the tests of the 'single patient use' of the defibrillator pads requested by the evaluation committee were taking place. The product was tested according to the Metronic (makers of the defibrillators) equipment, and they had to work to the standards within a set range of values. Two samples were tested and they did not pass the limits. Witness tabled a data sheet with the result of the tests (Doc 1).

Dr Axiak pointed out to witness that the MDH results go against the test results of an independent Italian laboratory, and led him to question the calibration of the measuring instruments.

Witness said that the MDH energy meter was last calibrated on 21st April 2017 and the next calibration is due in 2020. Calibration Certification was tabled (Doc 2). Also tabled in this context was the certificate from the Italian laboratory showing their test results on the product (Doc 3). Witness confirmed that the same meter was used to test all bids and only two samples from each bidder were tasted to have a level playing field. The brand name of the winning product was EF Medica.

Mr John Mary (Jimmy) Bartolo (228464M) called as a witness by the Board testified on oath that he was the Operations Manager Biomedical at MDH. His duties include testing samples sent by the CPSU. He tested two samples from each bidder and recorded the readings delivered by the simulator. He tabled a photo of the Appellants sample (Doc 4). Samples were thrown away after testing.

Dr Axiak stated that nowhere in the tender documents was it stated that the readings had to meet certain criteria related to the Metronic equipment. The tender did not ask for specific pads to agree with a specific machine – this was only indicated in the letter of rejection.

Dr Marco Woods Legal Representative of the CPSU referred the Board to Section 4 (1.1) of the Technical Specifications which stated that the electrodes were for use with Lifepack physiocontrol which indicated their ultimate use with the Metronic equipment.

The Chairman thanked both parties for the submissions and declared the hearing closed.

_____

This Board,

having noted this Objection filed by Cherubino Limited (herein after referred to as the Appellants) on 14 January 2019, refers to the claims made by the same Appellants with regard to the Tender of reference CFT 020-0549/18 listed as Case No 1269 in the records of the Public Contracts Review Board, and awarded by the Central Procurement and Supplies Unit (herein after referred to as the Contracting Authority).

Appearing for the Appellants: Dr Victor Axiak

Appearing for the Contracting Authority: Dr Marco Woods

Whereby, the Appellants contend that:

a) **their main concern refers to the fact that the Contracting Authority is claiming that their product gave unacceptable readings and after five uses it burnt out. In this regard, the Appellants maintain that the product was applied in sixty countries with high commendation and therefore the Appellants are concerned about the Contracting Authority's mode of testing the product and the calibration of the instruments used for such tests.**

This Board also noted the Contracting Authority's 'Letter of Reply' dated 22 January 2019 and its verbal submissions during the hearing held on 26 February 2019, in that:

a) **The Central Procurement and Supplies Unit maintain that the same testing procedures was carried out on all samples provided by the competing Bidders, so that a level playing field was maintained for all samples. In this regards, when the Appellants' samples were tested at 360 degrees, after five such tests, the pads began to burn up.**

This same Board has also noted the testimony of the witnesses which were summoned by the Public Contracts Review Board, namely,

1. **Eng Chris Attard Montaldo**
2. **Mr John Mary Bartolo**

This Board has also taken note of the documents submitted by the Central Procurement and Supplies Unit which consisted of statistics of test results.

This Board, after having examined the relevant documentation to this Appeal and heard submissions made by the parties concerned, including the testimony of the witnesses duly summoned, opines that the issue that merits consideration is the mode and results of the testing of the samples.

1. **It is an established procedure, especially in the medical field, that when a particular disposable medical product is requested, the Contracting Authority, quite appropriately, requests samples for the necessary testing, the results of such trials determining whether the product meets the technical specifications as stipulated in the Tender Dossier. In this**

particular procurement Tender, the item involved is "*Transthoracic disposable external pacing electrodes*."

2. **Cherubino Limited, in their submissions are contesting whether the procedure used for the testing of the samples was reliable enough to deem their product as being technically non-compliant. In this regard, this Board had to rely substantially on the documented results of the tests carried out by the Central Procurement and Supplies Unit, and more so, through the testimony of Eng Chris Attard Montaldo who actually supervised the necessary trials.**

3. **First and foremost, this Board is credibly convinced that the same procedure was carried out on all samples of the Bidders, so that the "*Level Playing Field*" principle was applied and confirmed by the technical witness, as follows:**

"*Avukat:* *Spjega ftit, kemm –il* sample *ħadt tal-prodott*

.

Xhud: *Tnejn. Żewġ* samples *kellna u għal kull offerta li kien hemm, qbadna żewġ samples ta' kull ditta. U ż-żewġ* samples *weħlu*."

At the same instance, this Board was vividly made aware of the procedure adopted during the testing of samples and in this regard, this Board would justifiably quote extracts from the credible testimony of Eng Chris Attard Montalto, as follows:

"*Avukat:* Fair enough

Xhud: *U jien bħala* professional *jiena nimxi skont ir*-recommendations *tal-magna li għandna.* I will not go outside those parameters, *għall-ebda mod u għall-ebda raġuni ta'xejn. Issa tgħidli*

l-prodott tiegħek huwa certified. I am not disputing that. *Jiena meta ġejt biex nittestjahom* they did not pass for me. At 70 joules and at 360 joules.

Avukat: *Għandek prova ta'dawn it-testijiet?*

Xhud: *Dażgur.*

Avukat: *Tista' tesebihom?*

Xhud: Yes yes. *Hawnhekk hawn tabella*. On the left hand side *hemm il*-preset, *l*-energy levels *li għażilna.* On the right hand side...

Chairman: *Kwalunkwe* sample *ġew ittestjati*, am I right?

Xhud: Yes yes. *Mela fit-tabella*, on the left hand side *għandek* the pre set values. *Jiġifieri jekk inti għandek* 70 joules *fuq il-magna u imbagad* on the right hand side *għandek ir-riżultati skond l*-energy meter *li għandna aħna*. *Issa l*-energy meters *tagħna jkunu kalibrati kull sena. Bażikament at* 70 joules *tani riżultat ta'* 63.1 joules. *Tgħidli* what does that mean? *Hawn dokument ieħor. Jekk tara* section 15, *dan huwa* recommended parameters *tad-ditta tad*-defibrillator *tagħna.* At 70 joules it must be between 65.1 and 74.9. *Il-fatt li dan ġie* 63.1 *ifisser li dak ħareġ minn dak it*-tolerance *li kien hemm* and I had no choice but to declare the product not suitable. *Imbagħad weħel ukoll* at 360 joules. *Ir-riżultat ġie* 328 *u suppost skond* section 15 *tad-dokument*, 360 joules should have come between 334.8 *and* 385.2. *Dan ġie* 328 so I had no choice but to declare that product not suitable."

This Board has also noted that, the test results were professionally documented and collaborates with the testimony of Eng Chris Attard Montaldo so that, this Board is justifiably convinced that the procedure carried out for the testing of samples was carried out in a transparent manner. At the same instance, one has to accept the fact that all samples were tested through the same procedure and the Appellants'

samples failed to be within the parameters of the technical specifications as duly dictated in the Tender Document.

4. **With regards to the Appellants' concern, in that the machine on which the tests were carried out might not have been properly calibrated, again, this Board would respectfully refer to the testimony of Eng Chris Attard Montaldo as follows:**

"*Xhud:* *Jien għandi* what we call energy meters. *Bażikament dawn jiġu kalibrati* once a year and they are certified once a year *u jekk għandek bżonn iċ-ċertifikat inġiblek ċertifikat li dak* l-energy meter *kien kalibrat. Jien ir-riżultat li jiena ħarist. Tista' ġġibli rapporti kemm trid. Jien għalija* the result I obtained *huwa importanti għalija għax jiena naf x'użajt u jiena naf x'metodu użajt*.

Avukat: *Jiena m'għandix dubju li ċert fuq il-metodu tiegħek. Aħna m'aħniex. Għalfejn? Mhux għax għandi xi dubju fil-kapaċita' tiegħek imma għaliex għandna prodott li qisu jintuża f'sittin pajjiż fid-dinja li din l-allegazzjoni qatt ma qamet u allura hija ta'*concern *kbir għall-klijent tiegħi. Meta għandek* data sheet *ta'laboratorju indipendenti li qed jgħidlek konsistentment li* this product satisfies the best requirements in the market *u qed jgħidlek x'inhuma dawn ir*-requirements. *Per eżempju intom semmejtulna li wara ħames xokkijiet ġew maħruqa. Il-laboratorju qed jgħidlek li wara ħamsin jiġu maħruqa. Qed nitkellmu fuq xi ħaġa li kważi kważi, qed iġġibni fid-dubju fuq is*-sample *li għandkom. Ħa mmorru lura fuq is*-sample. *Is*-sample *li intom kellkom, kif ħadtuh qabel xejn? Ġie sottomess lilkom mill*-bidder*?*

Xhud: *Għandi ritratt tas*-sample.

Chairman*:* *Ħa nagħmluha ċara. It*-testing *sar kif suppost kellu jsir u l-makkinarju li kellek kien kalibrat skont kif suppost?*

Avukat: *Jista' jkollna* calibration *ta'din il-magna?*

Chairman: *Meta' ġew ikkalibrati l-aħħar il*-meters?

Xhud: *Ħa nsiblek.*

Chairman: this was in April 2017.

Xhud: Next recalibration is 2020."

In conclusion, this Board opines that:

a) **the procedure used for the testing of samples was carried out in a professional and transparent manner, where each sample was uniformly tested on the same equipment;**
b) **the calibration of the machine on which tests were carried out was properly calibrated in accordance with the manufacturer's instructions so as to give correct and reliable results;**
c) **the statistical resultant data was properly documented.**

In view of the above, this Board,

i) **does not uphold the contentions made by Cherubino Limited;**
ii) **upholds the decision taken by the Central Procurement and Supplies Unit to award the Tender to Krypton Chemists Limited;**
iii) **directs that the deposit paid by the Appellants should not be refunded.**

Dr Anthony Cassar	Dr Charles Cassar	Mr Carmel Esposito
Chairman	Member	Member

21st March 2019