**PUBLIC CONTRACTS REVIEW BOARD**

**Case 1357 – CFT 020-0020/19 – Tender for the Supply of Guiding Catheters**

The publication date of the tender was the 11th January 2019 whilst the closing date was 31st January 2019. The estimated value of the tender (exclusive of VAT) was € 96,600 for three years supply

On the 5th July 2019 Jamesco Trading Co Ltd filed an appeal against the Central Procurement and Supplies Unit as the Contracting Authority contesting the decision to disqualify their bid as it was not technically compliant. A deposit of € 400 was paid.

There were six (6) bidders.

On 24th September 2019 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Lawrence Ancilleri as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

**Appellants – Jamesco Trading Co Ltd**

| | |
|---|---|
| Dr Joseph Bugeja | Legal Representative |
| Mr Philip Chircop | Representative |
| Ms Phylissienne Bugeja | Representative |

**Preferred Bidder – Europharma Ltd**

| | |
|---|---|
| Mr Alex Fenech | Representative |

**Contracting Authority – Central Procurement and Supplies Unit**

| | |
|---|---|
| Dr Marco Woods | Legal Representative |
| Ms Rita Zammit | Chairperson Evaluation Board |
| Ms Claudine Aitken | Member Evaluation Committee |

Dr Anthony Cassar, Chairman of the Public Contracts Review Board, welcomed the parties and before inviting submissions queried why according to the Information Sheet the tender was for three years supply but the recommended contract was only for one year. He was advised that the Contracting Authority had decided to reduce the contract to one year.

Dr Joseph Bugeja Legal Representative for Jamesco Trading Co Ltd stated that he wished to deal with two preliminary points. The letter of reply from the Contracting Authority was dated 11th July 2019 which meant it was outside the statutory ten calendar days allowed. Further the letter of rejection stated that the legal manufacturer is Marlborough MA USA which is an address not the name of a firm.

The Chairman commented that whilst this was irregular he was conscious of the very heavy workload that the Central Procurement and Supplies Unit faced. The Board still wished to hear the submissions on the case.

Dr Bugeja referred to Public Procurement Regulations 53 (8) and (6) which state that technical specifications shall not refer to specific origin and there shall be no market obstacles. He also referred to Regulation 232 which dealt with the proof of supply chain and that is what Appellants endeavoured to satisfy. Their product is imported from the Nederland but the mother company is based in the United States of America. The Evaluation Committee claims that this is different to the Certificate of Conformity which states that the origin is the Nederland. The Company is Boston Corporation of the USA, the product is manufactured in Mexico, its distributor is in Ireland but importation is from the Nederland. The Authority still did not accept the Certificate despite Appellant supplying all this information.

Dr Marco Woods Legal Representative for the Central Procurement and Supplies Unit said that the Nederland was the country of supply not of the manufacturing origin as stated on the Certificate and it was a clear mistake by Appellant. The Certificate does not follow what the technical specification required.

The Chairman stated that the issue was that the Certificate of Conformity does not meet the technical offer. He then thanked the parties for their submissions and declared the hearing closed.

End of Minutes

---

## Decision

## This Board,

**having noted this objection filed by Jamesco Trading Co Ltd (herein after referred to as the Appellants) on 5 July 2019, refers to the claims made by the same Appellants with regard to the tender of reference CFT 020-0020/19 listed**

**as case no 1357 in the records of the Public Contracts Review Board, awarded by Central Procurement and Supplies Unit (herein after referred to as the Contracting Authority).**

**Appearing for the Appellants: Dr Joseph Bugeja**

**Appearing for the Contracting Authority: Dr Marco Woods**

**Whereby, the Appellants contend that:**

a) **On a preliminary note:**

    i) **The Contracting Authority's 'Letter of Reply' is outside the statutory period of ten calendar days and**

    ii) **The Authority's 'Letter of Rejection' indicated that the legal manufacturer is referring to an address and not a name of the firm.**

b) **In their offer, they had supplied all the information relating to 'Country of Origin' on the certificate of conformity, however, the Authority is alleging that the certificate does not confirm the technical specifications requested.**

**This Board also noted the Contracting Authority's 'Letter of Reply' dated 22 August 2019 and its verbal submissions during the hearing held on 24 September 2019, in that:**

a) **The Authority insists that the certificate of conformity, as submitted by Appellants, indicated conflicting information between that shown on the certificate as 'Country of Origin' and that declared in the technical form, so that the Evaluation Committee had no other option but to deem Appellants' offer as technically non-compliant.**

**This Board would respectfully refer to the preliminary issues raised by Appellants and opines as follows:**

a) **With regard to the late submission of the Authority's 'Reasoned Letter of Reply', this Board acknowledges the fact that, such communication was outside the statutory period of ten calendar days. However, this Board notes that such an action on the part of the Authority was not capriciously made and this same Board is well aware of the workload which the said department has to process. At the same instance, this Board opines that, exclusion of the contents of the Authority's 'Letter of**

**Reply' should not prelude this Board from considering the merits of this case.**

**b) With regard to Appellants' second preliminary contention that, the 'Letter of Rejection' did not identify the correct legal manufacturer, this Board opines that such a deficiency on the part of the Authority is to be regretted and more care and attention should be devoted by the Authority when submitting such statutory correspondence. In this regard, this Board feels that such an error be noted but not considered as an obstacle for this Board to proceed with the hearing of the appeal.**

**This Board, after having examined the relevant documentation to this appeal and heard submissions made by the interested parties, opines that the issue that merits consideration is the certificate of conformity duly submitted by Appellants.**

1. **This Board would refer to clause 2.3 (Medical Materials & Devices) of section 4 of the tender document, wherein it is stipulated that:**

*"**2.3 Medical materials & devices***

*The following technical documentation is to submitted online through the prescribed Tender Response Format and by using the Tender Preparation Tool provided:*

i. *Detailed product technical document/ datasheet for product being offered.*
ii. *A valid Declaration of Conformity for product being offered and references to the relevant harmonized standards used (applicable if product falls under the medical device directive).*

*For products that do not fall under the medical device directive, a declaration is to be submitted confirming the classification of the product, together with certificate of compliance with the applicable legislation (as applicable)."*

**One must emphasize that the 'Certificate of Conformity' formed part of the technical specifications of the tender and the purpose for such a requirement is to ensure that the medical equipment or product is of the highest standard and conforms with the EU Directives regarding the supply of such delicate procurement.**

**2. This Board would also point out that the technical form represents the core of the tender document and although it is being acknowledged that, the technical form is a separate document from the Declaration**

**of Conformity, both documents form part of the stipulated technical specifications of the tender. At the same instance, the information indicated in the Certificate of Conformity must, with regard to country of origin and country of manufacture together with details of manufacturers, complement each other in both documents.**

3. **In this particular case, Appellants submitted a declaration of conformity showing the following information:**

*“* ***EC Declaration of Conformity***

***Legal Manufacturer:*** *Boston Scientific Corporation*
*300 Boston Scientific Way*
*Marlborough, MA 01752*
*USA*

***Manufacturing Sites:*** *Availmed S.A. de C.V.*
*Ave. Paseo Reforma No. 8950*
*C.P 22116 La Mesa*
*Tijuana, Baja California*
*MEXICO*

*Availmed S.A. de C.V.*
*Ave. Paseo Reforma No. 8950*
*C.Industrial lt. 001 Mz.105 No.20905 Int. A*

*Col.Cd. Industrial*
*Tijuana, Baja California*
*22444*
*MEXICO*

***European Representative:*** *Boston Scientific Limited*
*Ballybrit Business Park*
*Galway*
*IRELAND*

***Product:*** ***Mach1™ Guide Catheter***
*Design Dossier: 90262545*
*See Attachment for Additional Information.*
***Attachment A:*** *Curve Style Abbreviations and Style Families.*
***Attachment B:*** *UPNs and corresponding GTINs.*

*Class111, Rule 6 according to Annex IX of MDD."*

**However, in the technical form submitted by Appellants, the country of manufacture is shown as the Netherlands which throws a different light as to the origin of the product, so that there existed a contradiction to the certificate of conformity.**

4. **It must also be pointed out that the technical specifications fall under note 3, whereby no rectification is allowed and in this particular case any clarification requested on the submitted documentation would have amounted to a rectification. In this regard, this Board is justifiable satisfied that the Evaluation Committee adhered to the principles of equal treatment, transparency and self-limitation.**

5. **This Board would also point out that the 'Technical Form' represents the essence of the technical specifications of the product Appellants were offering, so that the details contained therein must represent what the certificate of conformity dictates and in this respect, the details contained in the certificate do not agree with what had been declared in the technical form submitted by Appellants. In other words, the technical form states that Boston Scientific is the manufacturer and the Netherlands is the country of manufacture (origin) whilst, the declaration of conformity mentions Boston Scientific, Boston, USA, as the legal manufacturer and Mexico, as the manufacturing site.**

6. **This Board would emphasize, as it has on so many occasions, that it is the duty and obligation of the tenderer to ensure that, prior to his submissions, all the requested information is provided for submission. At the same instance, this Board would also point out that, in case of doubt or misunderstanding on any of the clauses in the tender document, the bidder has the remedies to clarify or contest any of he clauses. In this regard, this Board notes that Appellants did not avail themselves of such available remedies prior to the submission of their offer.**

**In conclusion, this Board opines that:**

a) **The certificate of conformity submitted by Appellants does not confirm what has been declared in the technical form for the same product.**

b) **There existed no instances where the Evaluation Committee should have requested clarifications on the submitted documentation.**

**c) The Appellants had the remedies to clarify any misunderstanding on any of the stipulated requirements in the tender document, however, Appellants failed to avail themselves of such remedies, prior to the submission of their offer.**

**In view of the above, this Board,**

**i) Upholds the Contracting Authority's decision in the award of the tender,**

**ii) does not uphold Appellants' contentions,**

**iii) directs that the deposit paid by Appellants should not be refunded.**

| | | |
|---|---|---|
| Dr Anthony Cassar | Dr Charles Cassar | Mr Lawrence Ancilleri |
| Chairman | Member | Member |

*10 October 2019*