

PUBLIC CONTRACTS REVIEW BOARD

Case 1297 – CFT 020-1237/18 – Tender for the Supply of Hydroalginate with Silver Dressings, Sz 5x5cms and 10x10cms.

The publication date of the call for tenders was the 30th November 2018 whilst the closing date of the call for tenders was 20th December 2018. The estimated value of the tender (exclusive of VAT) was € 17,760.

On the 13th February 2019, Cherubino Ltd filed an appeal against the Central Procurement and Supplies Unit as Contracting Authority objecting that their bid was rejected as they failed to submit an ISO 13485 Certificate. A deposit of € 400 was paid.

There were six (6) bidders.

On 11th April 2019 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Mr Carmel Esposito and Mr Lawrence Ancilleri as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellants – Cherubino Ltd

Dr Francis Cherubino	Legal Representative
Mr Paul Calleja	Representative

Preferred Bidder – A M Mangion Ltd

Mr Desmond Bell	Representative
Mr Ray Vella	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Marco Woods	Legal Representative
Ms Marika Cutajar	Chairperson Evaluation Board
Ms Josette Camilleri	Member Evaluation Board
Mr Patrick Ghigo	Member Evaluation Board
Mr Mark Zammit	Representative

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

Dr Francis Cherubino Legal Representative of Cherubino Ltd said that the reason for refusal of their offer was that the Contracting Authority claims that an ISO 13485 Certificate had not been submitted with their bid. This case was identical to Case 1287 recently decided by this Board where it was upheld that the ISO Certificate was not required. The list of documents requested, under Section 4.2.3 makes no reference to ISO 13485 and was indeed not necessary as the Declaration of Conformity (DOC) covered it. The Malta Competition and Consumer Affairs Authority confirmed the above fact (Tabled as Doc 1).

Dr Marco Woods Legal Representative of the Central Procurement and Supplies Unit said that the ISO 13485 Certificate was specifically requested under the harmonised standards requirements of the tender document. It was a specific request as one of the relevant harmonised standards.

The Chairman stated that ‘harmonised standards’ is a generic term and if the Contracting Authority wanted a specific document they should refer to it by name.

Mr Mark Zammit (425874M) called as a witness by the Contracting Authority testified on oath that he is the Advanced Pharmacy Practitioner at the CPSU. He confirmed that the DOC is a certificate that covers all necessary harmonised standards of which there are over 300. The tender dossier does not refer to ISO 13485, it merely referred to harmonised standards without being specific.

The Chairman said that a basic condition in tenders is that the terms should be specific – generic terminology was not acceptable under European Court rulings especially in the medical field. He then thanked the parties for their submissions and declared the hearing closed.

This Board,

having noted this Objection filed by Cherubino Limited (herein after referred to as the Appellants) on 13 February 2019, refers to the claims made by the same Appellants with regard to the Tender of reference CFT 020-1237/18 listed as Case No 1297 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 Francis Cherubino

Appearing for the Contracting Authority: Dr Marco Woods

Whereby, the Appellants contend that:

- a) their main Objection refers to the fact that, the reason given by the Contracting Authority on why their offer was being rejected, was that, ISO 13485 Certification was not submitted by the former. In this regard, the Appellants' maintain that, nowhere, in the Tender Document, such a certificate was requested apart from the fact that the Document of Conformity (DOC) complied with the necessary requisites for the supply of this medicinal consumable.**

This Board has also noted the Contracting Authority's 'Letter of Reply' dated 21 February 2019 and its verbal submissions during the hearing held on 11 April 2019, in that:

- a) The Contracting Authority contends that, although, the Tender Document did not specify ISO 13485, the same Tender stipulated that, the Document of Conformity had to refer to one of the relevant**

harmonised standards. In this regard, the Appellants' offer did not include any of these standards.

This same Board also noted the testimony of the witness namely Mr Mark Zammit who was duly summoned by the Central Procurement and Supplies Unit.

This Board has also taken note of the documents submitted by Cherubino Limited which consisted of a declaration by the Malta Competition and Consumer Affairs Authority, marked as Doc 1.

This Board, after having examined the relevant documentation to this Appeal and heard submissions made by the parties concerned, including the testimony of the witness duly summoned, opines that the issue that merits consideration is the document submitted by Cherubino Limited.

- 1. This Board would refer to the reason given by the Contracting Authority for the Appellants' offers rejection which states that:**

“Reason for Rejection: No ISO 13485 Certification submitted as requested in Section 4 (2.3).”

In this respect, reference should also be made to Section 4 (2.3) ii which dictates the following:

“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).”

In this regard, this Board would respectfully point out that one of the main principles, in the formulation of the technical specifications of a Tender is, that, these must be clear, unambiguous and specific. In this particular case, although the Tender requested that the Declaration of Conformity must refer to the relevant harmonized standards, such particular standards are not being identified and neither is ISO 13485 mentioned as a requirement in the latter.

- 2. At the same instance, this Board took note of Doc A tabled by the Appellants during the Public Hearing, which consisted of a Declaration from the Malta Competition and Consumer Affairs Authority (MCCAA) confirming that it was not necessary for ISO 13485 to be included in the Declaration of Conformity, as follows:**

“The Directive does not specifically state that the applicable standards have to form part of the DOC, but they should be available upon request by the competent authority, (similar to other documentation like the Technical file etc).

3. This Board took consideration of the testimony of the witness namely, Mr Mark Zammit, an advanced pharmacy practitioner, who confirmed that the Declaration of Conformity is a certificate that covers all the necessary harmonised standards. Mr Zammit has also confirmed the fact that the Tender Dossier merely referred to harmonised standards without being specific.

4. This Board would respectfully emphasize the importance of stipulating exact requirements in the formulation of the Technical Specifications in that, the Contracting Authority must ensure that the technical specifications should:

- be precise in the way they describe the requirements;**
- be easily understood by the prospective Bidders;**
- have clearly defined, achievable and measurable objectives;**
- provide sufficient detailed information that allows bidders to submit realistic offers;**

- **not mention any brand names or other requirements which limit competition.**

In conclusion, this Board opines that,

- a) the Tender Document, with particular reference to Article 2.3 (ii) of Section 4, does mention the inclusion of harmonised standards in the Declaration of Conformity, but does not specify which standard and does not mention ISO 13485 to be included;**
- b) the reason given by the Contracting Authority for the Appellants' offer rejection is incorrect;**
- c) From the declaration of the Malta Competition and Consumer Affairs Authority duly tabled by the Appellants, the former confirms that it is not necessary to mention ISO 13485 in the Declaration of Conformity. Such declaration was also confirmed by the Witness;**
- d) The Declaration of Conformity submitted by the Appellants' fulfilled the Tender Requirements.**

In view of the above, this Board,

- i) does not uphold the decision taken by the Central Procurement and Supplies Unit in the award of the Tender;**

- ii) upholds the contentions made by Cherubino Limited, in that, the “Documents of Conformity” duly submitted did not request the inclusion of reference to ISO 13485;**

- iii) directs that the Appellants’ offer is to be included in the Evaluation Process;**

- iv) directs that the deposit paid by the Appellants is to be fully refunded**

Dr Anthony Cassar
Chairman

Mr Carmel Esposito
Member

Mr Lawrence Ancilleri
Member

18th April 2019