Case 1211 – CT 2246-2017 – Tender for the Supply of Polyurethane Foam Dressings

The publication date of the call for tenders was the 21st November 2017 whilst the closing date of the call for tenders was the 9th January 2018. The estimated value of the tender (exclusive of VAT) was € 281,269

On the 3rd August 2018, Krypton Chemists Ltd filed an appeal against the Central Procurement and Supplies Unit, Ministry of Health as Contracting Authority on the grounds that their offer was technically not compliant due to an invalid Declaration of Conformity. A deposit of € 1,769 was paid.

There were twelve (12) bidders.

On 25th September 2018 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:

Appellant – Krypton Chemists Ltd

Dr Steve Decesare	Legal Representative
Dr Katya Gatt	Legal Representative
Mr Matthew Arrigo	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Marco Woods	Legal Representative
Ms Marika Cutajar	Chairperson Evaluation Board
Mr Donald Attard	Member Evaluation Board
Mr Mark Zammit	Representative

Department of Contracts

Dr Franco Agius	Legal Representative

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

Dr Steve Decesare, Legal Representative of Krypton Chemists, stated that his clients' tender had been disqualified as the Contracting Authority claims that the Declaration of Conformity (DOC) was invalid. He asked the Board to hear the testimony of witnesses before making his submissions.

Ms Marika Cutajar (469772M) stated on oath that she was the Chairperson of the Evaluation Board and was a Principal Officer in the CPSU. She mentioned that the Evaluation Board consisted of one evaluator and a secretary. She had three years previous experience as chairperson of evaluation boards. In reply to questions she stated that she was not familiar with ISO requirements, and that the Evaluator has guidelines to follow regarding ISO and DOC requirements.

Mr Donald Attard (304763M) testified under oath that he was the Evaluator of the tender in this case. He was a Charge Nurse and evaluated medical devices for the CPSU and had previous experience of evaluations. He was *'au fait'* with the CPSU guidelines regarding standards expected relating to ISOs and was aware of the difference between products standards and quality standard systems. He was referred to the tender documents, Page 23 Section 4 which dealt with the technical specifications and stated that the Evaluation Board decided which ISO number was required according to the manufacturers' specifications. He agreed that ISO 13485 is a quality management system, but mentioned that it gives comfort to the CPSU that related products are manufactured according to the that ISO, and hence meet the tender requirements.

Mr Mark Zammit (425874M) testified on oath that he has been an Advanced Pharmacy Practitioner at the CPSU for five years and was in charge of technical evaluations. He explained the purpose of DOCs, and that there were various directives on self-declarations by manufacturers of devices. In this particular bid the DOC originating from Pharmaplast (copy tabled) shows the names of two notifying bodies – the notifying body in the text of the DOC (LNE/G-MED) is different to the letterhead which shows SGS as the originator. Article 16 of the Medical Directives specifies that there should only be one notifying body.

Witness further stated that once a decision had been made on the award of the tender Krypton indicated that they would appeal the decision – they then presented a certificate issued by SGS but showing LNE/G as the certifying party. It was up to the manufacturer to declare what harmonised standards it followed but the ISO details on the certificate in question were lacking the necessary particulars.

In reply to questions from Dr Decesare, witness said that he had prepared, in collaboration with the Malta Competition and Consumer Affairs Authority, checklists of what declarations were to be considered in tenders. It certainly was not acceptable to have two companies certifying a DOC. However he agreed, after further questioning by the Chairman, that the DOC submitted in the tender specified only LNE/G as the certifying body.

At this stage Dr Decesare objected to the fact that the Contracting Authority was bringing up fresh reasons for disqualifying the bidder – reasons which had not been included in their Letter of Reply. All ISO references in the DOC referred to product related standards not manufacturing standards. He produced a document referring to a 2016 MCCAA conference to which he wished to refer.

Dr Franco Agius, Legal Representative of the Director of Contracts, objected to any reference being made to a document that had no connection to this case.

After a short break to consider the objection, the Chairman directed that the document could not be tabled or discussed as it was not relevant to the case.

In reply to further questions from Dr Decesare, witness stated that the DOC must show only one body that guarantees the quality of the product in its entirety. He agreed that in the text of the DOC in this case only the name of LNE/G is mentioned - he also agreed that both names of notifying bodies appearing on the DOC were recognised by the European Union. Witness stated that the standards of manufacturing are related to the product – therefore the DOC must guarantee that the management related standards are met. The terminology in the tender asked for both standards and the requirements in Directive 93/42 to which this tender was tied made no distinction between product and manufacturer.

The Chairman asked witness if the applicable ISO numbers mentioned in the DOC are acceptable for the products in question. Witness replied that they are not acceptable as they lack to state the year of their introduction.

Dr Decesare stated that according to Public Procurement Regulations at evaluation stage the Contracting Authority must give its reasons for rejection. At that stage no mention was made by the Authority of a wrong ISO number, and it could not be introduced at this stage, as the appeal was based on the letter of rejection. If the Authority had mentioned other points in their letter of rejection Appellant would have had the time and the opportunity of dealing with them. Regulation 38.1 of the PPR emphasises the need for clear and unambiguous terms in a tender, which in this case stipulates product related certification. If the Contracting Authority also wanted manufacturing standards certification they should have asked for it – it is not equitable that disqualification takes place on matters that were not publicised. The DOC states what products the tenderer is offering and the only reference regarding standards is to products. The law obliges the Authority to issue clarifications if something is unclear – the onus is not on the bidder to seek clarification. If the Authority wanted both a product and a standards conformity certificate they should have asked for it. The rejection letter only mentioned the lack of an ISO 13485 certificate; the Authority cannot suddenly introduce additional reasons to justify their disqualification.

Dr Franco Agius brought up a number of Appeal Court sentences to sustain his submission that the Authority is obliged to correct mistakes if discovered at a later stage than evaluation. He mentioned Case 329/17 (possible to put right an oversight); Case 203/17 (during course of appeal can alter cause for rejection); Case 72/16 (changes allowed). If the Director of Contracts discovers mistakes he is obliged to bring them to attention – he made reference to past tenders when this happened, and even to instances when the Directorate made a mistake. In this case the Director felt that the DOC presented is not clear – Appellant had remedies (clarification or contract remedy) which they did not avail themselves of – they cannot now claim that the tender is not clear. A multitude of auditors on a DOC is not acceptable and it was irrelevant of Appellant to refer to similarities to other tenders (vide decision in PCRB Case 857/17).

Dr Decesare finally mentioned that there were two different bodies for certifying products and systems management – the Contracting Authority asked for product conformity and that was what was provided.

This Board,

having noted this Objection filed by Krypton Chemists Limited, (hereinafter referred to as the Appellants), on 3 August 2018 refer to the contentions made by the same with regards to the award of Tender of reference CT 2246/2017 listed as Case No 1211 in the records of the Public Contracts Review Board and awarded by the Central Procurement and Supplies Unit, (hereinafter referred to as the Contracting Authority)

Appearing for the Appellants: Dr Steve Decesare

Appearing for the Contracting Authority: Dr Marco Woods

Appearing for the Department of Contracts: Dr Franco Agius

Whereby,

a) **the Appellants are contesting the Contracting Authority's decision relating to the rejection of their offer in that, they insist that their "*Declaration of Conformity*", (DOC) was valid in all respects. In this regard, the Contracting Authority is alleging that the Appellants submitted an invalid "*Declaration of Conformity*", whereas the product is classified as Class II B and for which no reference is made to EN ISO 13485 – Quality Management, in the submitted "*Declaration of Conformity*".**

This Board has also considered the Contracting Authority's "*Letter of Reply*", dated 7 August 2018 and also its verbal submissions during the Public Hearing held on 25 September 2018, in that:

a) **The Central Procurement and Supplies Unit maintains that the "*Declaration of Conformity*", duly submitted by the Appellants, indicated two notifying bodies and not one, as should be in accordance with the relevant directive;**

b) **At the same instance, the Contracting Authority insists that the "*Declaration of Conformity*" submitted was not complete, as it did not make reference to EN ISO 13485 relating to the Quality Management.**

This Board has also noted the testimony of the following witnesses:

1. **Ms Marika Cutajar, duly summoned by Krypton Chemists Limited;**
2. **Mr Donald Attard, duly summoned by Krypton Chemists Limited;**
3. **Dr Mark Zammit, duly summoned by the Central Procurement and Supplies Unit.**

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, opines that the issues to be considered in this particular case are twofold namely:

a) **The notifying body/bodies;**

b) **The proper reference to the products' conformity.**

1. **<u>The notifying body/bodies</u>**

In this particular case, the Central Procurement and Supplies Unit is alleging that the "*Declaration of Conformity*", (DOC) submitted by Krypton Chemists Limited indicated two notifying bodies and not one, as imposed by the Directive 9342. At this stage of consideration, this Board would respectfully refer to the Appellants' submission in this regard, in that, it is an undisputed fact that the "*Declaration of Conformity*" is compiled on a letterhead of an accredited notifying body namely SGS, whilst the text dictates that the notifying body is LNE/G-MED as follows:

"***<u>Notifying Body</u>: LNE-G-MED (Address: Rue Gaston Bossier, Paris Cedex, France)***

<u>Notifying Body Identification No: (</u>0459))

***<u>Authorised Representative in the European Union:</u> M Devices Group, Marlborough House, Southport, UK*"**

From such documentation, although the text is written on another notifying body's letterhead, it is clearly indicated that the notifying body is one namely, LNE/G-MED, a French accredited body, however at the same instance, this Board finds it peculiar that a notifying body issued a "*Declaration of Conformity*" duly signed on a letterhead pertaining to a different notifying body and in this regard, this Board was not presented with any credible justification as to why such a "*Declaration of Conformity*" was not properly communicated on the official letterhead of the body making such an important and professional declaration. This Board would also refer to an extract from Dr Zammit's testimony which, in the opinion of this Board, is relevant and credible as follows

"***Avukat:*** ***Issa hawn hekk il-manifattur għamel dik id-dikjarazzjoni u beda billi jgħid, "we hereby declare these products". Issa d-dikjarazzjoni imbagħad qegħda ovvjament taħt "we hereby declare these products" u jien qed nara "notified body" wieħed. Jiġifieri int qed tieħu bħala declaration ukoll il-fatt li fil-letterhead, din il-kumpanija tispeċifika li hemm sistemi li huma konformi mal-13485 u mal-.....9001. Qed naqblu?***

Xhud: ***Nerġa' nirrepeti. Id-"declaration of conformity" huwa declaration ta'dokument intern. Żewġ faċċati. In all its entirety. U fid-dokument in all its entirety hemm referencza għal żewġ notified bodies. Fil-letterhead fuq hemm SGS. Jekk tara fit-text, hemm LNE/GMED. Id-declaration of conformity in its entirety qed issemmi żewġ notified bodies. Il-problema hija din, verament il-kumpanija trid tagħmel dikjarazzjoni li hija skont dawk l-istandards. L-issue hija imma li min qed jiċċertifika li qegħdin as per those standards? Ma jistax ikun hemm tnejn jiċċertifikaw. Dik il-kumpanija qed issemmi notified body LNE/GMED fit-text pero imbagħad very prominent fil-letterhead kemm tal-page 1 u tal-page 2 hemm notified body ieħor u that cannot be.***"

This Board was also informed that when Krypton Chemists Limited became aware of the award of the tender, they contested this decision with the Contracting Authority whilst at the same time, presented a "*Declaration of Conformity*" issued by SGS, a different notifying body from that of the original submission. Although such a submission is of no relevance to this appeal, this Board noticed that there was inconsistency in the submission of the "*Declaration of Conformity*" by the Appellants and although the same Board confirms that there was

only one notifying body, the presentation thereof could not be justified to represent the declaration which is expected in these circumstances and which Krypton Chemists Limited, through their experience in the field, are well aware of.

2. **<u>Reference to the product conformity</u>**

This Board refers to the Tender Document with special reference to section 4 2.3.2, which clearly stipulates that:

"*A valid declaration of conformity for product being offered and references to the relevant standards used*."

Although the above mentioned clause does not specifically mention the respective standards, it does provide sufficient information for the prospective Bidder to be aware of what is required. One has to acknowledge the fact that such Bidders are well versed in what a declaration of conformity is and what it consists of, through past tenders' experience and in this regard and in this Board's opinion, the Appellants were knowledgeable enough to discern what was required in a "*declaration of conformity*".

This Board also acknowledges the fact that, it is imperative and prudent for the Contracting Authority to ensure that its procurement, especially in the medical field conforms with the updated approved standards and by assuring such relevance in the "*Declaration of Conformity*", the Central Procurement and Supplies Unit is provided with the comfort that the product being offered will perform its intended functions without any risk to the patient.

Through the testimony of Dr Zammit, this Board was made aware that the ISO Standards denoted in the Appellants' submission are not in conformity with the requirements, as can be deduced from the following submissions:

"***Chairman:*** ***Jien dak li staqsejtkom. Iċ-ċertifikat juri one notified body. Għalhekk staqsejtkom imma dawk l-ISOs huma konformi?***

Xhud: ***L-istandards li jiġu msemmijin u jekk naraw dak id-dokument il-kbir li għidtuli li diġa' kien hemm mas-submission, dak fih hemm l-istandards kollha li huma relevanti għal din id-direttiva. Hemmhekk hemm 260 standard differenti. Jekk naraw kull standard***

***minnhom, dawk, għandu version, jgħidlek meta ġie first published, meta ġiet supercedes u kollha għandhom il-version tagħħom. Issa d-domanda li għamilt inti, sur Chairman, kienet jekk dawk l-istandards li hemm fit-text humiex tajbin jew le. Issa jien qed ngħid li standards biex inkunu nafu jekk hux tajbin jew le, irid ikun hemm il-version tiegħu. Għax l-istandards jiġu updated on a regular basis.*"**

It is a known and established fact that standards, in any profession or field, are updated on a regular basis, so that when a standard or directive is quoted, one has to indicate the reference code or number together with the date or year on which such a standard has been updated. This procedure is applied so that when a reference to a standard or directive is made, one should refer to the most recent.

The tender document dictated submissions of the references to the standards used and in this particular case, the product being offered falls under category class II B which relates to medical devices. For such products, a declaration of conformity relating specifically to standard EN ISO 13485 – Quality Management, had to be produced and in this regard, this Board notes that such a reference to this particular standard was not submitted by Krypton Chemists Limited.

An extract from the testimony of Dr Zammit will perhaps highlight the importance of such a standard as follows:

"***Avukat:*** ***Inti t-tender document talab li d-declaration of conformity tinkludi product standard applicable to the product kienet.***

Xhud: ***Of course. Din il-13485 hija xi ħaġa li jenfasiżżaw magħna l-MCCAA li mportanti li jkun hemm fid-DOC u jekk ma jkuxn hemm xi forma t'evidenza li huwa compliant mal-13485, fil-fatt m'għandux ikun aċċettabbli. U fil-fatt jien kelli ħafna korrispondenzi, very respectful u very productive mas-Sur Arrigo fuq dan ir-rigward, fuq l-importanza al-13485 along the years.***

Avukat: ***Mhux qed niddubita.***

Xhud: ***Imma anke l-fatt li jkun inkluż u jkun hemm referenza għalih fid-DOC. Fil-fatt għandi korrispondenza miegħu u fil-fatt dejjem ikunu, l-evidenza tiġi dejjem ippreżentata mis-Sur Arrigo u mill-kumpanija tiegħu***

***għall-offerti kważi kollha tiegħu. Fil-fatt din kienet something out of this world li ma kinetx. Mhix xi ħaġa li ma nafux. Ilna snin nitkellmu u fil-fatt kemm –il darba anke rringrazzjani tal-feedback u l-informazzjoni li nagħtihom. Ifisser li it is known l-importanza tagħħa fil-calls*.”**

From such a credible testimony, this Board establishes that, the tender document indicated sufficient information to enable the Appellants to be aware of what was requested in the declaration of conformity and this same Board confirms that the “*Declaration of Conformity*” submitted by the Appellants did not provide the necessary comfort to the Contracting Authority that their product complied with the respective approved standard.

3. **On a general note, during the submissions, this Board was made aware that the Evaluation Committee was composed of only one evaluator, the reason given for such a situation was due to lack of other members to serve on such committee. In this regard, this Board maintains that the Evaluation Committee for any tender should not be less than three members, so that the final assessment of the offers is concluded in an objective and transparent manner.**

4. **This Board would also refer to the Public Procurement Regulations whereby there are provisions for remedies to prospective bidders to seek clarifications or remedies prior to the closing date of submissions and in this regard, this Board notes that Krypton Chemists Limited did not avail themselves of such provisions. At the same instance, this Board also considered the fact that the Appellants are no newcomers to these types of tenders so that they are knowledgeable enough of what is normally required to be included in a "*Declaration of Conformity*" of a particular product.**

   In this regard, this Board opines that the information omitted in the "*Declaration of Conformity*" submitted by Krypton Chemists Limited was of great importance to the Contracting Authority to ensure that the product being offered by the Appellants is of the necessary approved standard and at the same instance, this Board confirms that such information was not present in the "*Declaration of Conformity*" submitted by the latter.

In view of the above, this Board:

i) **upholds Krypton Chemists Limited's contention in that there was only one notifying body indicated in the "*Declaration of Conformity*" which they submitted;**

ii) does not uphold the Appellants' contention that the "*Declaration of Conformity*" submitted was in accordance with section 4, article 2.3 (ii) of the tender document;

iii) upholds the Central Procurement and Supplies Unit's decision in the award of the tender;

iv) instructs the Contracting Authority to avoid situations where the Evaluation Committee is composed of less than three members;

v) takes into consideration items i) and iv) above and recommends that an amount of € 1,000 from the deposit paid by Krypton Chemists Limited, is to be refunded.

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

9th October 2018