

PUBLIC CONTRACTS REVIEW BOARD

Case 2081 –CfT020-3221/24 - CPSU 5279/24 – Supplies - Tender for the Supply of Sterile Synthetic Surgical Gloves Size 6

3rd March 2025

The Board,

Having noted the letter of objection filed by Dr Clement Mifsud Bonnici, Dr Calvin Calleja and Dr Krista Refalo acting on behalf of Ganado Advocates, acting for and on behalf of Krypton Chemists Limited (hereinafter referred to as the "Appellant"), filed on the 29th of August 2024;

Having also noted the letter of reply filed by Dr Alexia J Farrugia Zrinzo and Dr Leon Camilleri acting on behalf of the Central Procurement and Supplies Unit (CPSU) (hereinafter referred to as the "Contracting Authority"), filed on the 4th of September 2024;

Having heard and evaluated the testimony of the witness, Mr Matthew Arrigo (representative of Krypton Chemists Limited, the "Appellant"), as summoned by Dr Leon Camilleri, acting on behalf of the Contracting Authority;

Having heard and evaluated the testimony of the witness, Mr Edmond Balzan (Evaluator), as summoned by Dr Calvin Calleja, acting on behalf of Krypton Chemists Limited, the "Appellant";

Having taken cognisance of and evaluated all the acts and documentation filed, as well as the submissions made by the legal representatives of the parties;

Having noted and evaluated the minutes of the Board sitting of the 20th of February 2025, hereunder reproduced:

Minutes

Case 2081 –CfT020-3221/24 - CPSU 5279/24 – Supplies - Tender for the Supply of Sterile Synthetic Surgical Gloves Size 6

The tender was published on the 27th February 2024 and the closing date of the call for tenders was the 20th March 2024.

The estimated value of this tender, excluding VAT, was € 54,000.

On the 29th August 2024 Krypton Chemists Ltd filed an appeal against the decision of the Central Procurement and Supplies Unit to disqualify their offer on the grounds that it was technically not compliant.

A deposit of € 400 was paid.

There were seven bids.

On the 20th February, 2025 the Public Contracts Review Board composed of Dr Vincent Micallef as Chairman, Mr Lawrence Ancilleri and Dr Ing. Damien Gatt as members convened a public hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – Krypton Chemists Ltd

Dr Calvin Calleja	Legal Representative
Dr Krista Refalo	Legal Representative
Mr Matthew Arrigo	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Alexia Farrugia Zrinzo	Legal Representative
Dr Leon Camilleri	Legal Representative
Ms Bernice Gauci	Chairperson of the Evaluation Committee
Ms Krystle Refalo	Secretary of the Evaluation Committee
Mr Edmond Balzan	Evaluator
Ms Maria Curmi	Representative

Recommended Bidder – Alfred Gera & Sons Ltd

Mr Kevin Muscat	Representative
Ms Josette Calleja Fenech	Representative

Dr Vincent Micallef, Vice-Chairman of the Public Contracts Review Board, welcomed the parties and, prior to inviting submissions, proposed that since there are three appeals which are identical, except for the size of the gloves, they should be dealt with concurrently at one hearing. This was agreed to by all the parties.

Dr Calvin Calleja, Legal Representative for Krypton Chemists Ltd, said that the appellant would be relying on the written submissions. On the preliminary point regarding the timing, appellant raised this point to illustrate the lack of good administrative behaviour and does not wish to take it further.

Dr Leon Camilleri, Legal Representative for the Central Procurement and Supplies Unit (CPSU), stated that the 19th August was a normal working day, and the point regarding administrative behaviour is dealt with in the written submissions. He then went on to deal with the actual appeal and noted that the technical offer form must be completed fully at submission stage. A 'yes' answer must indicate what it refers to – simply stating '1 to 10' puts the evaluators in difficulty, as it puts the onus on them to search for the answers. The packaging of the samples had a warning sign indicating the possibility of an allergic reaction and indicates that some other materials were used in their manufacture. This warning did not give the necessary comfort to the evaluator that the product was safe to use. The Evaluation committee acted wisely in the circumstances.

Dr Daniel Buttigieg, Legal Representative for Kemimport Ltd, said that the preferred bidder had similar points to raise as those of the Contracting Authority, and it is up to the Board to decide on those points. There is doubt about the safety of the gloves, and that aspect is an extremely sensitive matter. No rectification was possible on the offer.

Mr Matthew Arrigo (188094M), called to testify by the appellant, stated on oath that he is a Director of Krypton Chemists Ltd and has nine years' experience of dealing in medical products and has handled different types of gloves. He prepared the tender submission. The product offered was latex free, as the product offered was synthetic and therefore not made of natural products. The appellant had declared that the product was latex free by indicating 'No' in the technical form. The reason for rejection said that the product offered by the appellant complies with the specification in the tender but could not indicate what products were used. Witness could not recall if there were any other

communications from the Authority. Accelerators are chemical ingredients used in the production of gloves and are unrelated to latex.

In reply to questions from Dr Camilleri, witness stated that appellant is the importer of gloves manufactured by others. By definition, the use of the word synthetic means that the product is free of latex, which is a natural product. The manufacturer of gloves subject of this tender also manufactures gloves which include latex. Asked if he could explain why there was a warning on the packaging, witness said that this might be because accelerators are used in the material.

Mr Edmond Balzan (472665M), called to testify by the Contracting Authority, stated on oath that he has eight years' experience of evaluating tenders and was the sole evaluator of this tender. On receipt of samples, he noticed that the packaging indicated a warning that material used during manufacturing may cause allergic reactions and caution must be exercised. This warning meant that the witness was not comfortable to send the gloves for testing, since these gloves are used by surgeons during operations with the attendant risk to the user and the patient. Exhibits of all three sizes (EB1, EB2 and EB3) submitted as samples by the appellant to the TEC were tabled in evidence.

Questioned by Dr Calleja, witness said that the technical offer by the appellant declared that the gloves were non-latex but merely stated '1 to 10'. This latter point was not raised in the letter of rejection. Witness went on to explain that synthetic polychloroprene means that the product does not contain latex, and the use of this synthetic material is indicated in items 1 and 2 in the technical literature. When referred to the packaging note, which also states that the product is not made of natural latex, witness said that this still does not give comfort to the TEC in view of the warning. As the request for samples was regulated by Note 3, rectification was not possible, and the warning did not need clarifying.

In reply to questions from Dr Camilleri, witness confirmed that the gloves have to be sterile, as they are used by surgeons, and he had sought advice from the nursing staff on this matter. The samples exhibited (EB1, EB2 and EB3) did not show the latex-free symbol, unlike the samples provided by the recommended bidder, tabled as exhibit EB4.

Replying to questions from Dr Buttigieg, witness said that there was a distinction between 'not made from latex' and 'latex free'. Cross contamination was possible.

This concluded the hearing of testimonies.

Dr Calleja said that this appeal is based on three grievances – the first two can be taken in tandem, namely product compliance and the TEC's disproportionate decision; the third grievance is that the TEC went further than the tender requirements. The technical literature declared that the product is sterile synthetic polychloroprene, which by definition is an artificial material. The Contracting Authority makes it clear why latex is not accepted. What was submitted was free of latex, as indicated on the technical order form (DOC KSL 2) and on the packaging artwork, which states that the product does not contain natural latex. The offer therefore meets all the tender criteria, and once all criteria were met, then the price becomes the criterion. This is in line with the Nexans France Case T-415/10 regarding the obligation to stick to the parameters of the tender. The TEC ignored the technical form, the literature, and relied on a clause in the packaging. The reference in that clause to 'other materials' does not mean that it contains latex. There is no doubt that the product offered meets the tender requirements, and if there is any doubt or inconsistency, then proportionality demands clarification under Note 3. The appellant would not have been given an advantage by this move. There is no mention of latex in the exclusion letter.

Dr Calleja continued by saying that, following the receipt of the rejection letter, the appellant requested disclosure of information (KCL4), from which it transpires that gloves submitted by other bidders (KCL7) may contain the same provisions as those offered by the appellant. Bidders were therefore not treated similarly and equally. The appellant's product was technically compliant, but it was deprived from competing.

Dr Buttigieg stated that the fact that the product is not latex-free is indicated by the lack of the relevant symbol. The gloves in question could have been cross-contaminated in the manufacturing process. The warning on the package indicates that one cannot rely on there being no latex content, and this can affect the safety of patients. The price difference in the offers reflects the difference in the manufacturing process.

Dr Camilleri referred to the testimony of the appellant and stated the witness is not a medical professional, is not involved in the manufacturing process, and has not provided sufficient proof of what it is alleging. No proof has been provided from the manufacturer to justify its claim that there is no risk of latex allergy. When asked what other materials were included, the witness did not provide a convincing answer. The tender makes it clear that the possibility of latex is a matter of concern. The fact is that the sample states that it is not made of natural latex but does not state that it is latex-free – this is enough to create doubts in situations where latex is a matter of concern. The request for a sample is a Note 3 matter, and clarification would not change what is stated on the packaging. Proportionality must be used carefully in cases involving health matters.

Dr Calleja said that the technical specifications did not request products with a latex-free symbol but a simple phrase, and no proof has been provided that the two requirements are aligned. Reference to the manufacturing process is purely hypothetical, as it is not known.

Dr Buttigieg noted that the whole point of the latex symbol is that it indicates all steps are taken to ensure there is no cross-contamination.

Dr Camilleri said that the symbol and the wording on the package are not the same, and the latter did not state "latex-free". It is up to the appellant to prove what takes or does not take place in the manufacturing process.

There being no further submissions, the Chairman thanked the parties and declared the hearing closed.

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 20th of February 2025.

Having noted the objection filed by Krypton Chemists Limited (hereinafter referred to as the "Appellant") on the 29th of August 2024 and refers to the claims made by the same Appellant with regards to the tender of reference CfT020-3221/24 - CPSU 5279/24 listed as case No. 2081 in the records of the Public Contracts Review Board.

Appearing for the Appellant:

Dr Calvin Calleja and Dr Krista Refalo

Appearing for the Contracting Authority:

Dr Leon Camilleri and Dr Alexia Farrugia Zrinzo

Whereby, the Appellant contends with respect to:

The First ground of appeal: The Appellant's bid was technically compliant

- The Appellant is, with respect, perplexed that the Contracting Authority found its product to be technically non-compliant. It confirmed adherence to the functional specifications by answering 'Yes' in the Technical Offer Form-as this Board will be able to testify.
- Moreover, the technical literature submitted by the Appellant-which remains confidential and may not be disclosed without the Appellant's consent-proves that the product is compliant with Specification No. 1.1 on multiple occasions. Firstly, the heading to the Product Specifications is: "Sterile Polychloroprene Surgical Powder-Free Glove Palm Textured" which, in itself, as a form of synthetic rubber confirms that the product is latex-free, or rather, ensures prevention of a Type I Latex Allergy, as it is known in the industry.
- This is reiterated in the Product Description section under the "material" characteristic.
- The samples provided by the appellant, including the packaging artwork, again confirms that the product being supplied is "sterile synthetic polychloroprene surgical gloves". Barring the inclusion of the term "polychloroprene", this is a reproduction word for word of the Tender's title.
- To put the matter beyond any reasonable doubt-although the Appellant submits that the TEC should have already reached this stage on the basis of the previous confirmations provided-the packaging contains a note which categorically and explicitly reassures the Contracting Authority that "*this product is **not** [emphasis added] made from natural rubber latex*".
- The TEC was allegedly dissuaded by the inclusion of a separate warning on the packaging which alerts users to the possibility that: *other materials used during the manufacturing process may cause allergic reactions in some users. Particular caution must be exercised if the user has any known or suspected hypersensitivities.*
- The packaging forms one whole and must be read as a whole. The different notes on the packaging cannot be read in isolation-as the TEC purportedly did-to disqualify the Appellant from the call and award the contract to a bidder whose price was 10.65% higher than that of the Appellant.
- The reasonable man, to use the same yardstick, would have come to the conclusion that the warning intends to alert users that "*other materials [may have been] used during the manufacturing process [which] may cause allergic reactions [other than latex allergies] [emphasis added]*".

The second ground of appeal: the TEC's decision to disqualify the appellant is disproportionate

- If the warning on the packaging artwork created any doubt for the TEC on the conformity of the Appellant's product with the required technical specifications, the TEC could have easily requested a clarification from the Appellant.
- A request for clarification was allowed according to the tender requirements since specifications are a Note 3 matter:

No rectification shall be allowed. Only clarifications on the submitted information may be requested. Tenderers will be requested to clarify the submitted information within five (5) working days from notification.

- This would not have resulted in an undue advantage being given to the Appellant over other bidders for it would have been only an opportunity to clarify existing information which was already in the possession of the TEC.
- However, the Contracting Authority opted for the more disproportionate option of disqualifying the Appellant instead of the more proportionate request for clarification. In doing so, it breached its obligation to treat the Appellant proportionately in terms of Regulation 39 of the PPR.

The third ground of appeal: the contract is recommended for award to an offer which complies with additional requirements not stated in the tender document

- The Appellant suspects that the TEC recommended the contract to be awarded to the Recommended Bidder on the basis of additional requirements which were not declared in the tender documentation.
- Prior to submitting this appeal, the Appellant requested the disclosure of the packaging artwork and the technical literature of the product offered by the Recommended Bidder. The Contracting Authority disclosed this information on the 27th of August 2024, 6 days after the Appellant's request on the 21st of August 2024 and only 2 days before the deadline to lodge an appeal lapsed.
- Apart from confirming that it is latex-free, the technical literature for the recommended product declares on page 81 that it is also free of accelerators, that is:

"[it is] made from synthetic polymers and a 100% chemical accelerator-free formulation, these sterile surgical gloves eliminate the risk of a Type I latex allergy and the potential of developing Type IV chemical allergies caused by chemical accelerators".

- Accelerators are chemicals used in the process of manufacturing synthetic rubber. They are also capable of triggering allergic reactions in individuals who are sensitive to these specific compounds or known to cause Type IV allergies and sensitivities, as they are known in the industry.

- However, these chemicals do not trigger a latex allergy in the user. Therefore, the fact that the Recommended Bidder's product is capable of being produced without these compounds has, or should have, no effect on the TEC's evaluation. It is immaterial whether the product submitted by the Appellant is free of these chemicals because this was not a requirement in the tender document.
- If, as the Appellant suspects, the Recommended Bidder's bid was chosen over its own bid because of this additional characteristic, then the Contracting Authority fell foul of the obligation to treat all economic operators equally.
- It also actively shifted the goalposts. This on its own is already a breach of procurement principles but the-so far alleged-fact that it gave an undue advantage to the Recommended Bidder over the Appellant is an aggravating factor.

The Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 4th of September 2024 and its verbal submission during the hearing held on 20th February 2025, in that:

On the First Grievance - The Appellant's Bid was Technically Compliant

- The objector states that it was perplexed that the contracting authority deemed the offer as technically non-compliant. Such a sentiment was certainly reciprocal since as will be explained in this reasoned letter of reply, there is no way how the objector's product can be deemed to be technically compliant.
- The fact that the objector marked as 'yes' the functional requirements of the technical offer form, is certainly not enough for a technical evaluation committee to decide on the technical compliance of an offer. The offer should then be substantiated with details in the technical offer form itself and further substantiated with the literature and samples.
- The technical specifications state as a functional specification that these gloves are to be used "*For all surgical procedures where latex allergy is a concern for either healthcare workers or patients*". The objector marked this specification with a 'yes' in the technical offer form but in the column which requested "*Details on the Offer's specifications for the respective requisite*" the objector did not provide any information and just included the numbers '1-10', numbers which should have presumably been included in the following column which was left blank.
- Since the objector declared with a 'Yes' the column which mandated that these gloves will be used in situations where there is a latex allergy, the objector should have specified in the column requesting details, how this requisite was met, for example by stating that 'the gloves are latex free' and referring to the specific clause of the technical literature where this is provided (and not a general '1-10' for all specifications).
- The technical literature of the objector does state that the product is '*Polychloroprene Surgical Glove, Powder Free, Polymer Coated, Sterile*' and that the Material is '*Synthetic Polychloroprene Latex*' however in

no instance does it state that it is free of natural latex. Whilst the packaging states that the product is not made of natural latex, it does not exclude it from the manufacturing process.

- **The use of natural latex could thus not be excluded, especially when the packaging of the same product did not rule out other materials used during the manufacturing process!** If the literature states that the material of the product is *Synthetic Polychloroprene Latex*, but does not rule out other materials used in the manufacturing process, then natural latex cannot be ruled out.
- Moreover, as already stated, the objector did not give any details and corresponding clause from the literature that the product can be used in situations where latex allergy is a concern. In a similar situation in case 2016 decided by this Honourable Board on the 5th of June 2024, it was argued by CPSU that:

The missing details were however in the column entitled "Details on the offer's specifications for the respective requisite". The only "detail" which the objector has given in relation to such requirement in this column was that "table plate can be tilted" which in our humble opinion is not a detail at all, as it is a repetition of the requirement to which you have already replied with a Yes. The detail would have certainly been, how much does the table tilt. [...] Moreover, the objector did not even substantiate this specification by any literature since the brochure presented as technical literature with the technical offer only stated that the table can be tilted but did not state the degree that this table can be tilted to.

- This Board upheld the arguments of CPSU and stated that *"This Board now refers to the Technical Offer form as submitted by the appellant whereby in the column "Details on the Offer's specifications for the respective requisite" it was the same appellant who provided information in detail to all criteria except for clause 2.6. A simple "Yes" was submitted in relation to this column for clause 2.6. This Board agrees with the Evaluation Committee that this is a Note 3 issue."*
- The Technical Evaluation Committee had therefore to conclude the evaluation on the basis of the information it had in hand that is, a technical offer form with an empty detail column and technical literature and packaging which did not exclude latex. Since technical specification 1.1 could not be confirmed, the offer had to be rejected.

On the Second Grievance - The TEC's decision to disqualify the appellant is disproportionate

- In this grievance the objector states that Evaluation Committee should have requested a clarification rather than move on to reject the offer.
- CPSU respectfully disagrees with the objector, since the clarification which the objector is suggesting is substantively a rectification which would have changed the technical offer.
- This Honourable Board in case 2016, where a similar argument was also made decided that:

Moreover, for the column "Reference in the technical literature where this is being stated/shown", the appellant submitted "See attached docs". The Board notes that the literature did not make reference to the total load that the

bed table can withstand. This would have been a 'Note 2' matter: However, once the Evaluation Committee has duly identified non-compliance issues in the Technical Offer Form, which falls under the remit of 'Note 3', it would have been futile to request any rectifications for missing details in the technical literature.

- In this present case, **the objector in its letter of objection is agreeing that technical specifications are note 3**. Such details are therefore unable to be changed. The appellant had every opportunity to provide the necessary details at bidding stage (if these effectively exist) and cannot expect to make the technical submission at this stage. If the evaluation committee had to accept the suggestion of the objector and permit a clarification, this would in substance be a rectification and would be in breach of the principle of self-limitation and of equal treatment of bidders.
- The evaluation committee was therefore in line with all general principles of public procurement, including the principle of proportionality.

On the Third Grievance: The contract is recommended for award to an offer which complies with additional requirements not stated in the tender document

- The objector alleges that the recommendation of the evaluation committee was based on qualities of the recommended product which were not part of the technical specification.
- CPSU strongly rebuts to this claim, as the evaluation committee evaluated all the offers in line with the technical specifications as published.
- CPSU submit that this third grievance is highly speculative and has not legal or factual basis.
- Any added features of an offered product (unless prohibited by any technical specification) do not have any bearing on the evaluation process. The product of the recommended bidder was recommended for award because it was the cheapest technically compliant product offered. The objector's product was not technically compliant.

This Board, after having examined the relevant documentation to this appeal and heard submissions made by all the interested parties including the testimony of the witnesses duly summoned, will now consider Appellant's grievances.

Preliminary Observation: Evaluation by a Single Evaluator

The most fundamental flaw identified in this case is the fact that the tender was evaluated by only one evaluator. As highlighted in an online document entitled "*Standard Operating Procedures (SoP) Guidelines for Tender Evaluation Committees (TEC) Version 1.1 Department of Contracts*", it is clearly stated that a TEC should

consist of a minimum of three evaluators or any odd number, unless otherwise approved by the Director of Contracts. This procedural requirement is not merely advisory but forms a part of the established principles for tender evaluation, as also corroborated by the Public Procurement Policy Notes on the Department of Contracts website, particularly PPN 40.

The importance of multiple evaluators lies in the collective and balanced judgment they bring to the process, reducing the risk of bias and ensuring a more objective evaluation of tenders. By evaluating the tender in isolation, the process was inherently flawed, and the decision made by a single evaluator cannot be considered in line with best practices. It is imperative that these guidelines are in place and be adhered to rigorously to ensure transparency, objectivity, fairness, and consistency in public procurement.

On the Second Grievance - The TEC's decision to disqualify the appellant is disproportionate

The Board has carefully examined the functional specification requirements for the gloves, specifically Section 3 Spec number 1.1, which stipulates that the gloves are intended "*For all surgical procedures where latex allergy is a concern for either healthcare workers or patients*".

Upon thorough examination of the physical evidence submitted by the Contracting Authority during these proceedings, the Board notes that the packaging for each pair of gloves explicitly contains the following declarations:

- "*Sterile Synthetic Polychloroprene Surgical Gloves*"
- "*Note: This product is not made from natural rubber latex*"
- "*Warning: Other materials used during the manufacturing process may cause allergic reactions in some users. Particular caution must be exercised if the user has any known or suspected hypersensitivities*"

The Board determines that the declarations "*Sterile Synthetic Polychloroprene Surgical Gloves*" and "*Note: This product is not made from natural rubber latex*" constitute sufficient *prima facie* evidence that the product meets the fundamental requirement of being suitable for use where latex allergy is a concern. The presence of these clear statements on the packaging provided adequate submitted information to warrant a clarification request pursuant to Note 3 of the tender documentation, which expressly permits clarifications on submitted information within five working days from notification.

Such clarification would have appropriately allowed the Appellant to elucidate the nature of the "*other materials*" referenced in the warning statement and to confirm whether these materials could potentially compromise the product's suitability for use in latex-sensitive environments. The Evaluation Committee's failure to seek this permissible clarification before proceeding to disqualification represents a procedural deficiency.

Consequently, this Board finds substantial merit in the Appellant's grievance regarding disproportionality. The Contracting Authority's decision to summarily disqualify the Appellant without availing itself of the clarification mechanism explicitly provided for in the tender documentation was manifestly disproportionate and contravenes the fundamental principle of proportionality enshrined in Regulation 39 of the Public Procurement Regulations (PPR).

On the First and Third Grievances

Given that the requisite clarification request was improperly omitted from the evaluation process, the Board determines that the first grievance concerning technical compliance and the third grievance regarding alleged preferential treatment of the Recommended Bidder are premature and cannot be definitively adjudicated at this juncture. A proper evaluation process, including appropriate clarifications, must first be completed to establish the factual basis for these claims.

Conclusion

The evaluation process in the present case exhibits fundamental procedural deficiencies, specifically:

1. The failure to constitute a Technical Evaluation Committee with the minimum required number of evaluators, thereby compromising the objectivity and reliability of the assessment; and
2. The failure to request clarification on submitted information as expressly permitted under Clarification Note 3 of the tender documentation.

The Board therefore directs that the evaluation be comprehensively reviewed and that a proper evaluation process be conducted in accordance with established procurement principles and procedures. This review must include the appointment of an appropriately constituted Technical Evaluation Committee comprising at least three evaluators to ensure a process characterized by objectivity, transparency, consistency, and fairness.

The Board,

Having evaluated all the above and based on the above considerations, concludes and decides:

- a. To uphold the Appellant's Letter of Objection and contentions related to the second grievance concerning disproportionality;
- b. Declares the Appellant's first and third grievances as premature and indeterminate at this stage pending proper evaluation;
- c. Revokes the recommendation of award made in favour of the Recommended Bidder;
- d. Directs that the evaluation be reviewed and that a proper evaluation process be conducted, orders the reintegration of the Appellant's bid in the re-evaluation process, which re-evaluation shall implement the Board's findings;
- e. Directs that this review should include the appointment of a newly and appropriately constituted TEC, with at least three evaluators, to ensure an impartial, objective and transparent process;
- f. Directs that bidders be requested to extend the validity period of their respective bids, if required;
- g. Directs that the deposit paid by Appellant to be reimbursed in full.

Dr Vincent Micallef
Chairman

Dr Ing. Damien Gatt
Member

Mr Lawrence Ancilleri
Member