

PUBLIC CONTRACTS REVIEW BOARD

Case 2246 – CPSU7465/25 – Tender for the Supply of 3-4 ml Plasma Tubes with Lithium Heparin and gel separator

8th June 2026

The Board,

Having noted the letter of objection filed by Dr Maria Lisa Buttigieg on behalf of Mamo TCV acting for and on behalf of 3Tech Limited, (hereinafter referred to as the appellant) filed on the 23rd April 2026;

Having also noted the letter of reply filed by Dr Alexia Farrugia Zrinzo and Dr Leon Camilleri acting for the Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 30th April 2026;

Having also noted the letter of reply filed by Dr Douglas Aquilina, Dr Mark Attard Montalto and Dr Samira Briffa acting for the Drugsales Limited (hereinafter referred to as the Interested Party) filed on the 30th April 2026;

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

Having noted and evaluated the minutes of the Board sitting of the 14th May 2026 hereunder-reproduced;

Minutes

Case 2246 – 671 – CPSU 7465/25 – Tender for the supply of 3-4ml Plasma Tubes with Lithium Heparin and Gel Separator.

The Tender was issued on the 20th of January 2026, and the closing date was 11^h February 2026.

The estimated value of the tender, excluding VAT, was €18,837.60

On 23rd April 2026, 3 Tech Ltd., lodged an appeal against Central Procurement and Supplies Unit (CPSU)– the Contracting Authority, in accordance with Regulation 270 of the Public Procurement Regulations.

On the 14th of May 2026, the Public Contracts Review Board (PCRB), composed of Mr Kenneth Swain as Chairman, Mr Keith Victor Grech and Mr Lawrence Ancilleri as members, convened a public hearing to consider the appeal.

A deposit of €400 was paid.

There were Ten bids.

The attendance for this public hearing was as follows:

Appellant – 3 Tech Ltd.

Dr Maria Lisa Buttigieg – Legal Representative.

Mr Claude Bugeja – Company Representative.

Ing. Joseph Bugeja – Company Representative.

Contracting Authority – Central Procurement and Supplies Unit (CPSU).

Dr Alexia Farrugia Zrinzo – Legal Representative.

Dr Leon Camilleri -- Legal Representative.

Ms Bernice Gauci – Chairperson.

Recommended Bidder – Drugsales Ltd.

Dr Douglas Aquilina – Legal Representative

Mr Adrian Busuttil – Company Representative.

Mr Reuben Demanuele – Company Representative.

Dr Alec Sladden – Observer.

Opening Statements

The Chairman welcomed the parties present and formally opened Case Number 2246 in the records of the PCRB. The Chairman identified the Appellant as 3 Tech Ltd, the Contracting Authority as the Central Procurement and Supplies Unit (CPSU), and representative of the recommended bidder, Drugsales Ltd.

The Chairman opened the session by stating that, since the arguments and grievances in both cases, 2245 and 2246, respectively, were the same, all parties agreed to hold one hearing encompassing both appeals.

The Appellant and the Contracting Authority had no witnesses, and there was no need for the presence of the Evaluation Board in relation to this hearing.

The Chairman invited the legal representative for the Appellant to make his submissions.

Submissions

Submissions by Dr Maria Lisa Buttigieg (for the Appellant)

Dr Buttigieg stated that both appeals concerned different product supplies, but the bid submitted by 3Tech Ltd. was identical. The reason for the rejection was that it was deemed *“invalid since the name and position of the person signing the Declaration of Conformity (DOC) are not listed”*.

In this case, the Authority could have requested a clarification. Both the Authority and the Recommended Bidder argued that neither a clarification nor a rectification could be made. 3Tech Ltd. disagreed with this position.

The Contracting Authority confirmed that all documents had been submitted, and that the only issue concerned the Declaration of Conformity.

The Declaration of Conformity lacked the name and position of the undersigned. The DOC confirmed that the products conformed with the applicable law, bore the Company stamp, and included the signature of the person certifying the document.

It only lacked the name and position of the signatory. There was no need for a new document; the Committee merely had to request the name of the person. This would have been fair and just, as the substance of the DOC would have remained unchanged.

The offer submitted by 3Tech Ltd. was substantially lower than that of the recommended bidder. The Committee could have sought clarification, and therefore the appeal should be upheld.

Submissions by Dr Leon Camilleri (for the Contracting Authority)

Dr Leon Camilleri argued that the evaluation had been carried out in a rigorous and transparent manner to ensure that every bidder was treated equally. The technical offer in this bid was subject to Note 3, under which rectification is not permitted. He quoted the requirement from the offer:

“Signature on Declaration of Conformity. Name, Surname and function within the manufacturing company of signatory”.

The bidder marked “yes”; however, this was not reflected in the Declaration of Conformity. The Company stamp was not requested; only the name, position, and signature were required. He also quoted from the General Rules Governing Tenders:

“No rectification shall be allowed in respect of the documentation as accompanied by Note 3 in Clause 5 of the Instructions to Tenderers. Only clarifications on the submitted information in respect of the latter may be requested. No clarifications shall be allowed where there is no doubt that the submitted technical offer does not comply to the requested specifications”.

Dr Camilleri noted that, had there merely been missing letters, it could have been accepted; however, since the required information was entirely absent, no clarification or rectification was permissible. The Evaluation Committee’s decision was the only fair and justified decision to take and should therefore be confirmed.

Submissions by Dr Douglas Aquilina (for the Recommended Bidder)

Dr Aquilina stated that this was not a matter of clarification. The document presented was not a valid Declaration of Conformity. The Committee had not requested the signature capriciously. The Declaration of Conformity is regulated by European law, and the requirement stems directly from that legislation. The DOC submitted was null and invalid. He quoted the law:

“A Declaration of Conformity shall contain the name and function of the person who signed it, as well as an indication for, and on behalf of whom that person signed”.

The document submitted was therefore not a valid Declaration of Conformity.

Replica by Dr Maria Lisa Buttigieg (for the Appellant)

Dr Buttigieg stated that the case referred to in the reply was not comparable, since in that case nothing had been presented, whereas 3Tech Ltd. had submitted a certificate. A clarification would have resolved the issue entirely.

Replica by Dr Alexia Farrugia Zrinzo (for the Contracting Authority)

Dr Zrinzo stated that a clarification was not permissible and that, had it been allowed, it would in fact have constituted a rectification.

Replica by Dr Douglas Aquilina (for the Recommended Bidder)

Dr Aquilina noted that all documents should have been submitted by the prescribed deadline.

Conclusion of the Hearing

The Chairman, Mr Kenneth Swain, thanked all parties present and formally concluded the hearing. The Board would communicate its decision in due course.

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 14th May 2026.

Having noted the objection filed by 3Tech Limited (hereinafter referred to as the Appellant) on 23rd April 2026, refers to the claims made by the same Appellant with regards to the tender of reference CPSU7465/25 listed as case No. 2246 in the records of the Public Contracts Review Board.

Appearing for the Appellant: Dr Maria Lisa Buttigieg

Appearing for the Contracting Authority: Dr Leon Camilleri & Dr Alexia Farrugia Zrinzo

Appearing for the Recommended Bidder: Dr Douglas Aquilina

Whereby, the Appellant contends that:

a) ***First Grievance - All required documents were duly presented***

The tender dossier for the Tender required, for medical devices and in vitro diagnostic devices, that bidders submit at tendering stage a "valid Declaration of Conformity for product being offered and references to the relevant harmonized standards used," together with other technical literature and labelling requirements. No further formalities for the DoC were specified in the tender dossier. The Tender required a valid DoC, which the Appellant maintains that it submitted a valid DoC at tendering stage. Indeed, in the case in question, the Contracting Authority does acknowledge that the DoC was in fact submitted by the Appellant, since it purports in its decision dated 10th April, 2026 to reject the bid because the DoC allegedly did not list the signatory's name or position. This is decisive confirmation that the required DoC was presented with the Appellant's technical offer, and that the Contracting Authority's objection relates to form rather than to the existence of the required document or to the underlying substantive conformity of the product. Therefore, the Appellant has submitted all required documentation within the applicable timeframes.

b) ***Second Grievance - No basis for immediate exclusion in the Tender***

Without prejudice to the Appellant's position that the DoC submitted by them was valid, the Tender documents did not prescribe that a perceived deficiency in signatory details on the DoC must lead to automatic exclusion without first seeking clarification. Accordingly, disqualification on this basis, without first requesting clarification, is disproportionate and procedurally unfair. The Instructions to Tenderers set out, in detail, the items required at tendering stage, including the Tenderer's Technical Offer, literature, and, for medical devices and IVDS, the DoC, but they do not set any express evaluation rule that an alleged formality relating to the DoC signatory details must result in disqualification. The Special Conditions and Specifications, which expand upon the general conditions and technical obligations, likewise do not state that a tender is to be excluded on this basis without first requesting clarification. The tender rules must be applied as written; they cannot be supplemented by an automatic exclusion rule applied after the fact. It has been well established in the relevant public procurement jurisprudence that Contracting Authorities must adhere to the tender dossier and refrain from introducing non-written requirements at evaluation stage.

c) ***Third Grievance - Duty to Seek Clarification***

Without prejudice to the above, should the Board consider that there was an ambiguity or deficiency concerning the identification of the DoC signatory, the Contracting Authority was under a duty to request a clarification before resorting to exclusion. The tender's own "Notes to Clause 5" state that, although no rectification is allowed, "only clarifications on the submitted information may be requested," with a five working day deadline for tenderers to clarify. This clause allows the Contracting Authority to resolve exactly the kind of minor, non-substantive issue it has raised,

namely, confirming the name and position of the person who signed a document that was otherwise submitted on time with the tender.

The principle of proportionality under the Procurement Regulations (S.L. 601.03), as recognised in prior decisions of this Honourable Board, requires that exclusionary measures go no further than necessary to protect the integrity of the tender process. A simple clarification request would have been enough to confirm who signed the DoC and in what capacity. Exclusion is the most severe sanction available and is clearly excessive for a matter of form that was neither required by the tender dossier nor relevant to the technical compliance of the product offered. This approach is reflected in past PCRB decisions where the Board emphasised the obligation to clarify non-material oversights.

Moreover, the principles of good administration and fair procedure require contracting authorities to use the least burdensome means to resolve doubts where the required document has been submitted but a minor detail is unclear, rather than resorting to automatic rejection. The Tender expressly directs such matters to the clarification mechanism, and the Contracting Authority's failure to use that mechanism deprives the appellant of a fair opportunity to address a minor ambiguity. This also undermines transparency and equal treatment, since bidders are entitled to have their offers evaluated in accordance with the rules and procedures the Contracting Authority itself published in the Tender documents. The rejection is also inconsistent with the Tender's evaluation process, which provides that the contract shall be awarded to the cheapest compliant offer. Excluding a bidder without first seeking clarification on a minor aspect of a submitted document risks distorting this process by prioritising formalities not required by the Tender over the public interest in obtaining compliant supplies at the best price. The recommendation to award to another bidder highlights the real prejudice caused by failing to seek clarification.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 30th April 2026 and its verbal submission during the hearing held on 14th May 2026, in that:

a) ***On the First Grievance: All required documents were duly presented.***

With reference to the first grievance, CPSU submits that it is not disputing the fact that a declaration of conformity was submitted with the objector's offer. The reason for rejection clearly states that the Declaration of conformity did not include the name and position of the person signing it.

b) ***On the Second and Third Grievance: No basis for immediate exclusion and the duty to seek clarification.***

The objector argues in these 2 grievances that the tender document did not state that a deficiency in the signatory details of the DOC will lead to automatic exclusion of the offer, and that there was a duty on the part of the contracting authority to seek clarification. CPSU submits that the name

and position of the person signing the DOC was a mandatory technical requirement in the technical offer form for which the objector clearly marked with a YES.

Despite confirming that the declaration of conformity included the name and function of the person signing it, such name and function were missing from the declaration submitted.

Since the declaration of conformity and the technical offer form are note 3, no rectification could be made and thus the offer could never be accepted as compliant.

The General Rules Governing Tenders in section 16.3 provide that: *No rectification shall be allowed in respect of the documentation as accompanied by Note 3 in Clause 5 of the Instructions to Tenderers. Only clarifications on the submitted information in respect of the latter may be requested. No clarifications shall be allowed where there is no doubt that the submitted technical offer does not comply to the requested specifications.*

This Board also noted the Preferred Bidder's Reasoned Letter of Reply filed on 30th April 2026 and its verbal submission during the hearing held on 14th May 2026, in that:

- a) Whilst Drugsales Limited has not seen the document that was submitted by 3Tech Ltd and purported to be a Declaration of Conformity, it appears uncontested that the document submitted lacked an indication of the name and position of the person signing the said document.
- b) In the regard, it is to be noted that this tender refers to an in-vitro medical device and the tender required submission of the Declaration of Conformity in line with the In-vitro Medical Diagnostic Devices Regulation (In-Vitro Device Regulation 746 of 2017).
- c) This requirement arises in Specification 2.3(ii) which clearly refers to technical documentation that needs to be submitted online through the prescribed Tender Response Format with each offer at tendering stage.
- d) It does not appear to be contested by 3Tech Ltd, that a Declaration of Conformity had to be submitted, and that this was a requirement.
- e) The appeal of the objector is - with all due respect - constructed on a fundamentally wrong premise. Tech Ltd is alleging that it did submit a valid a Declaration of Conformity, and that inter alia the contracting authority demanded additional information which goes beyond a Declaration of Conformity. This is fundamentally incorrect. The tender document specifically requires submission of a valid Declaration of Conformity in terms of the Directive.
- f) A Declaration of Conformity is defined and regulated by law, and has certain requirements in order to be valid. The In vitro Medical Diagnostic Devices Regulation (In-Vitro Device Regulation 746 of 2017) clearly states that a DoC must contain certain information at a minimum:

Article 17 - EU declaration of conformity

1. The EU declaration of conformity shall state that the requirements specified in this Regulation have been fulfilled. The manufacturer shall continuously update the EU declaration of conformity. The EU declaration of conformity

shall, as a minimum, contain the information set out in Annex IV and shall be translated into an official Union language or languages required by the Member State(s) in which the device is made available.

- g) Annex IV lists the minimum requirements of a Declaration of Conformity, whereby paragraph 10 states: *ANNEX IV - EU DECLARATION OF CONFORMITY The EU declaration of conformin shall contain the following information:*
- 10. Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed. signature.*
- h) Since the objector submitted a document that did not indicate the name and position of the person signing the document, the document is evidently not a valid Declaration of Conformity.
- i) Therefore, the objector failed to submit a valid Declaration of Conformity, which was a fundamental document required upon submission of the tender.
- j) Furthermore, the technical offer form of the tender specifically listed the requirements for the Declaration of Conformity, whereby point 6.16 specifically requires the name, surname and function of the signatory.
- k) Therefore, in reply to the specific grievances raised by the objector:
- First grievance: This grievance is unfounded because in actual fact the objector did not submit a valid Declaration of Conformity
 - Second grievance: This grievance is also unfounded since the tender required submission of a valid Declaration of Conformity, a valid Declaration of Conformity was not submitted by the objector, and therefore the tender had to be rejected. The Contracting Authority did not impose additional conditions or request additional information that was not already requested in the tender document.
 - Third grievance: This grievance is also unfounded. This is not a matter of clarification, but a matter of a document which was not submitted. A valid Declaration of Conformity was not submitted by the objector.
- l) As to the objector's reference to principles of proportionality, it is to be noted that the principles of proportionality and equal treatment require as a fundamental principle of public procurement that tenderers are not allowed to submit new documents past the deadline for submission of tenders. The objector did not submit a valid Declaration of Conformity. Allowing submission of a new document after the deadline would be a clear breach of the tender conditions and would be tantamount to submitting an offer after the deadline for submission of the tender, which is something completely prohibited and goes against fundamental principles of fair competition and equal treatment of bidders.
-

This Board, after having examined the relevant documentation to this appeal and heard submissions made by all the interested parties, shall now proceed to consider the Appellant's grievances.

The Appellant contends that it submitted all documentation required by the tender dossier within the prescribed timeframes, including the Declaration of Conformity. The Appellant argues that the Contracting Authority itself acknowledged the submission of the DoC and that the alleged deficiency related solely to the absence of the signatory's name and position, which the Appellant characterises as a purely formal issue rather than a substantive defect affecting the validity of the document itself.

Conversely, the Contracting Authority submits that although a document purporting to be a Declaration of Conformity was indeed submitted, the document failed to comply with the mandatory requirements expressly stipulated in the tender documentation and the applicable regulatory framework, since it omitted the name and function of the signatory. The interested Party similarly argued that the omission rendered the submitted document invalid as a declaration of Conformity in terms of the applicable European regulatory requirements governing in-vitro medical devices.

The Board notes that the core dispute concerns whether the document submitted by the Appellant constituted a valid Declaration of Conformity satisfying the requirements of the tender and the applicable law. The Board further notes that the Appellant's grievances are intrinsically linked to this central issue and shall therefore be considered collectively:

- a) The Board considers it necessary to distinguish between the mere submission of a document and the submission of the mandatory information required to render such document compliant with the tender conditions and the applicable legal framework. In the present case, the issue under dispute is not whether a document entitled "Declaration of Conformity" was physically submitted by the Appellant, since this is not contested by the parties. Rather, the central issue concerns whether the submitted document contained all the mandatory information expressly required under the tender documentation and the applicable regulatory framework, including the identification and function of the signatory.
- b) The tender documentation, in Section II, Part 6 of the technical offer form clearly required the bidder to complete all fields in the checklist and confirm whether the requested information was included in the submitted documentation. Furthermore, point 6.16 specifically required the "Name, Surname and function within the manufacturing company of signatory".
- c) The Board also notes that the Technical Offer Form was expressly subject to Note 3, whereby rectifications are prohibited and only clarifications may be requested in limited circumstances.
- d) Furthermore, Public Procurement Note 40, Section 4 – Policy Content and Guidelines stipulates that:

*"In the eventuality that it transpires that **the submitted information/documentation** [Board Emphasis] is or appears to be **ambiguous, contrasting or not sufficiently explicit and clear** [Board Emphasis], Contracting Authorities/Entities, in their capacity as Evaluation Committees, shall*

*request the concerned Economic Operators to **clarify the necessary information** [Board Emphasis]/ documentation, within the appropriate Time Limit.”*

- e) Moreover, rule 16.3 of the General Rules Governing Tenders (V4.10) provides in a very clear manner that:

"No clarifications shall be allowed where there is no doubt that the submitted technical offer does not comply to the requested specifications."

- f) In this present case, the Board considers that the omission of the signatory's name and function did not constitute an ambiguity or lack of clarity capable of clarification, but rather an omission of mandatory information expressly required by both the tender documentation and the applicable legal framework.
- g) Hence the Board points out that compliance with the requirement would necessarily have required the Appellant to provide new information which was entirely absent from the submitted document at tender stage. Such exercise would therefore not constitute a permissible clarification but an impermissible rectification of the technical offer.
- h) The Board emphasises that tenderers bear sole responsibility for carefully examining the procurement documents and ensuring that all mandatory **information** [Board Emphasis] and documentation are properly submitted within the prescribed time limits.
- i) Had the Evaluation Committee permitted the Appellant to supplement the missing information after the closing date for submissions, this would have undermined the principle of fair and equal treatment vis-à-vis the other tenderers who submitted complaint documentation ab initio.
- j) Accordingly, the Board finds that the Evaluation Committee acted in accordance with the applicable procurement rules and principles when it rejected the Appellant's offer as technically non-compliant.
- k) Therefore, the Board find no merit in the Appellant's Grievances.

The Board,

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

- a) Does not uphold Appellant's Letter of Objection and contentions,
b) Upholds the Contracting Authority's decision in the recommendation for the award of the tender,
c) Directs that the deposit paid by Appellant not to be reimbursed.

Mr Kenneth Swain
Chairman

Mr Lawrence Ancilleri
Member

Mr Keith Victor Grech
Member