

IN THE PUBLIC CONTRACTS REVIEW BOARD

25th October 2026

Re: Objection 716 - CPSU 5887/26 - Tender for the Supply of Instrument Protectors Medium

Reply of **Central Procurement and Supplies Unit** (CPSU) on behalf of the Department of Health as the Contracting authority to the reasoned application lodged by **Medina Healthcare Limited** (the Objector).

A call for tenders for the Supply of Instrument Protectors Medium had been published and a number of bids were submitted. Following an evaluation process the tender was recommended for award to **Drugsales Limited** (the Recommended Bidder), having the cheapest offer satisfying all the required specifications.

The Objector's offers not recommended for award since there was a cheaper compliant offer which was recommended.

The objector felt aggrieved with the decision of the evaluation committee and filed its objection, based on 3 grievances.

CPSU humbly disagrees with the grievances raised and is hereby presenting its reply.

Submissions

On the First Grievance: The product of the recommended bidder bears a CE marking and claims conformity with the Medical Devices Regulation to which it is not entitled.

1. The objector in this first grievance submits that the product which CPSU is seeking to procure is neither a Medical Device nor an accessory to a medical device in terms of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, and thus could not be CE-marked, raising the argument that the product offered by the recommended bidder presented a product on the strength of a regulatory status which does not exist.

2. CPSU disagrees with this line of argumentation.

3. First and foremost, it is the responsibility of the manufacturer to categorise the product it produces and adhere to the requirements and obligations of the category which in its judgment is the correct one for the product it is producing.

4. Secondly, CPSU which must also ensure that any such classification is correct, verified with its experts and stakeholders, that instrument protectors do fall within the parameters of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices as will be further explained during the sitting;

5. For this reason, the grievance raised shall be deemed unfounded both in fact and at law and should therefore be rejected.

On the Second Grievance: The offer of the recommended bidder cannot be compliant with the tender document.

6. The Objector submits that the tender document imposes different requirements for products falling within the parameters of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and those which do not fall within these parameters. The objector thus argues that either way, the recommended bidder is not compliant since the declarations presented for medical devices are not valid, and the documentation which should have been presented for products which are not medical devices, is lacking.

7. CPSU refers to the submissions made in relation to the first grievance which apply equally for this grievance.

8. For these reasons this grievance ought to be rejected.

On the Third Grievance: Breach of Clause 3.2.1 of Section 3 and of the principle of self-limitation.

9. The Objector in this grievance states that the evaluation committee breached Clause 3.2.1 of Section 3 and of the principle of self-limitation. This is also unfounded in fact and at law;

10. The evaluation committee ensured that all tender requirements are fulfilled and came up with a conclusion, and thus a recommendation, on the basis of the documents they had in hand, evaluated against all clauses of the tender document and the appliable rules and regulations, and came up with their conclusion accordingly.

11. For these reasons this grievance should also be rejected.

CPSU hereby reserves its right to present further evidence and submissions both written and orally to further substantiate its reply in relation to the said objection throughout the hearings.

In view of the above, the objection lodged by the objector ought to be rejected in full, whilst the decision of the Evaluation Committee confirmed, and the relevant deposit forfeited.

CPSU will however not object to the refund of the deposit if the appeal is withdrawn before the hearing.

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