

IN THE PUBLIC CONTRACTS REVIEW BOARD

21<sup>st</sup> April 2026

**Re: Objection 666 - CPSU6399/25 - Tender for the Supply of Sterilization Reels (Various Sizes)**

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

A call for tenders for the Supply of Sterilization Reels (Various Sizes) was issued by CPSU on the 16th of September 2025.

A number of bids were submitted and following an evaluation process the tender was recommended for award to **Medina Limited (the recommended bidder)**.

The objector's offer was not recommended for award since it was found to be technically non-compliant for the following reason:

*Further to samples received, there was a discrepancy in relation to specification 2.9, whereby specifications indicate that the CE marking must be printed or stamped on the inner carton or the plastic roll. However, the samples received have the CE marking printed only on the outside of the carton box. The marking does not appear on the inner carton or on the plastic roll, as requested. Therefore, the bid is deemed as technically non-compliant.*

The Objector filed an objection based on 4 grounds of appeal.

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

**Submissions**

**On the First Ground of Appeal - Compliance with CE Marking requirement**

1. The objector in this ground of appeal argues that product fulfils the CE marking requirement since the CE marking is clearly affixed to the product packaging.
2. CPSU submits that, it is not contesting the fact that the product offered was CE certified and it may also be the case that the product offered by the objector was CE marked in a clear manner on the packaging, however tender technical criterion 2.9 requires that the product "Must have CE marking printed or stamped on the inner carton/plastic roll"
3. As will be demonstrated to the Board, the CE marking of the product offered by the objector was not on the inner carton or plastic roll, but was elsewhere, thus the offered product was not in compliance with technical specification 2.9;

4. Specification 2.9 was specific and did not merely require that the product is CE certified or that there is a CE marking anywhere on the product – the specification requested that the CE marking is printed or stamped on the inner carton/plastic roll. A CE marking anywhere else on the packaging of the product would mean non-compliance with the said specification.
5. For this reason, this first ground of objection should be rejected.

**On the Second Ground of Appeal – Inconsistency of Placement Requirement with the Applicable Standards.**

6. The objector states that the placement of the CE marking on the outer packaging rather than on the internal sterilisation components is inconsistent with the applicable European standards and established industry practice.
7. This is factually incorrect since such standard does not exist and there are manufacturers which produce their products with prints on the inner carton/plastic roll. There is nothing which is non sterile having such marks on the on the inner carton/plastic roll.
8. Moreover it is important to note that in the environments where the sterilisation reels are used, the box is not allowed for hygiene reasons.
9. Additionally, CPSU submits that such grievance should have been brought up during the applicable time frame for the filing of an action in terms of regulation 262 of the Public Procurement Regulations before the closing time for the submission of offers. Once this time frame lapsed there is a juris et de juris presumption that the specifications as published have been accepted and thus whoever submits an offer should observe such specifications.
10. The objector also had ample time to ask for clarifications as per procurement procedure on this matter and indeed chose to do so in certain matters but failed to seek clarification and/or guidance on the issue of the place of the CE mark for which it is now objecting and arguing that the specifications as published are not in line with industry standards and practices.
11. This has been also the position taken by our Court of Appeal. In fact in the decision of the 10<sup>th</sup> of January 2023 in the names **All Clean Services Limited v. Ministeru għall-Edukazzjoni et**, the Court states that:

*7. Din il-Qorti taqbel ma' dak li osserva l-Bord li kull min kien interessat, jekk ma kienx jaqbel ma' xi kundizzjoni fis-sejha, skont irRegolamenti applikabbli, seta' agixxa, bil-mezzi li jagħtuh l-istess Regolamenti, biex jipprova jimpunja dik jew dawk il-kundizzjonijiet. Mhux leċitu li l-oblatur iħalli l-proċess għaddej, u wara, jekk jitlef il-kuntratt, jallega li kundizzjoni fis-sejha ma kellhiex tkun hemm għax "kompletament irrilevanti".*

*8. Hu veru li l-kundizzjonijiet tax-xogħol tal-ħaddiema huma regolati b'ligijiet oħra, u hemm regolamenti li jagħtu poter lill-awtorità kompetenti tissindika fuq dawk il-kundizzjonijiet, però, dan kien ikun argument li kellu jitressaq fl-istadju preparatorju*

*għall-proċess tal-ghażla tal-oblatur preferut. Jekk ir-rekwiżit ta' ftehim kollettiv huwa parti mill-kundizzjonijiet li kellhom jigu sodisfatti minn kull oblatur, is-soċjetà appellanti kellha taderixxi ruħha ma' dak rikjest. Din il-Qorti osservat diversi drabi li dak rikjest fid-dokumenti tas-sejha għall-offerti jridu jigu kollha sodisfatti.*  
(Added emphasis)

12. Similarly, in the decision of the Court of Appeal in the names **Vassallo Builders Ltd v. Wasteserv Malta Ltd** et decided on the 6<sup>th</sup> of May 2025 it was stated that:

*... jekk VBL dehrilha li r-rekwiżit inkwistjoni kien illegali, hija setgħet tattakka dak il-kriterju fl-istadju ta' qabel l-gheluq tas-sottomissjoni tal-offerti, u dan bil-mod kif imsemmi f'Regolament 262 Regolamenti dwar l-Akkwist Pubbliku. La hija naqset milli tagħmel hekk, u s-sejha għall-offerti kienet tobbligaha tressaq kopja tal-«Final or Provisional Acceptance Certificate or equivalent», mela allura, VBL kienet marbuta li tressaq tali dokumentazzjoni, anke jekk dehrilha li dik id-dokumentazzjoni ma kinitx meħtieġa minhabba s-setgħat tal-kumitat tal-avalwazzjoni li jwettaq ilverifiki kollha meħtieġa, jew inkella għaliex dak il-kumitat seta' jsib linformazzjoni minn fuq l-internet.* (Added emphasis)

13. For all these reasons, CPSU submit that this second ground of appeal should also be rejected.

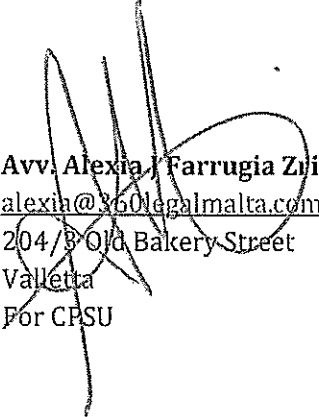
**On the Third Ground of Appeal – Disproportionate and Formalistic Assessment and on the Fourth Ground of Appeal – Concluding Remarks.**

14. In this third grievance the objector argues that the product that it has offered is fully compliant in substance and that the disqualification is disproportionate.
15. CPSU submits that the objector cannot state that the product is fully compliant when it is evident that the CE mark is not *printed or stamped on the inner carton/plastic roll, in breach of clause 2.9 of the Technical Specifications.*
16. Moreover with reference to the question of proportionality, and the question of substance over form, it is important that this Board also understands that clause 2.9 was not made capriciously but for a reason.
17. The outer pack of a sterilisations strips roll cannot be moved in the theatres, and thus the only way that a clinician can ensure CE certification before using the product is by referring to the inner carton/plastic roll.
18. The print/stamp of the CE Certification on the inner carton/plastic roll is a specification in itself and not merely intended for a proof of CE Certification, which is another specification which although related, is not one and the same with the requirement for CE Certification, which is a requirement in all medical devices. Having the CE mark elsewhere is thus irrelevant for the purposes of specification 2.9 as it is not intended to merely prove CE Certification!
19. For all these reasons, CPSU submit that the third and fourth ground of appeal should also be rejected.

CPSU hereby reserve its right to present further evidence and submissions both written and orally to further substantiate their 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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