DALLIPARIS
ADVOCATES



15th October 2026

Public Contracts Review Board
Notre Dame Ravelin,
Floriana,
Malta

Medina Healthcare Limited

vs

[1] Central Procurement and Supplies Unit

[2] Drugsales Ltd

CPSU 5887/26
Tender Name: Tender for the Supply of Instrument Protectors Medium

REASONED OBJECTION

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Whereas, this is an objection being filed by Medina Healthcare Limited (hereinafter "Medina" and/or "Appellants"), in accordance with, *inter alia*, Regulation 270 of the Public Procurement Regulations, Subsidiary Legislation 601.03 (hereinafter the "PPR").

Whereas, Medina participated in the tender with reference CPSU 5887/26 (CfT ID 13687913), together with other economic operators, following a call issued by the Central Procurement and Supplies Unit (hereinafter "CPSU" and/or "the Contracting Authority"), for the Supply of Instrument Protectors Medium for a period of thirty-six (36) months, with an option for a further extension of twelve (12) months, and for an estimated quantity of 279,000 units.

Whereas, the sole award criterion of the tender is price, the contract falling to be awarded to "the tenderer submitting the cheapest priced offer satisfying the administrative and technical criteria", as Clause 6.1 of the Instructions to Tenderers expressly provides.

Whereas, by means of a letter dated 5th October 2026, the Appellants were informed that their offer was not successful, and that the tender was being recommended for award to Drugsales Ltd (hereinafter "Drugsales" and/or "recommended bidder"):

> *"Thank you for participating in the above-mentioned procurement procedure. However, this Entity regrets to inform you that the procurement proposal submitted by your company was not Choose an item. compliant. The main reason/s why your procurement proposal was non-compliant is/are as follows:*
>
> *Reason for Rejection: A cheaper technically compliant offer was recommended.*
>
> *The procurement was recommended for award to Messrs Drugsales Ltd for the amount of €53,010.00 excluding VAT, this being the cheapest priced offer satisfying the administrative and technical criteria."*

Whereas, by virtue of a request for information dated 5th October 2026, the Appellants requested the Contracting Authority, *inter alia* in accordance with Regulation 40 of the PPR, to disclose the names, brands and models of the products offered by the recommended bidder, and by means of an email dated 6th October 2026 the Contracting Authority informed the Appellants that the product offered by the recommended bidder is of the brand "Blue Medical", product code BM33002585 (hereinafter the "Blue Medical Instrument Protector") .

Whereas the Appellants feel aggrieved by the decision to recommend for award the bid by Drugsales, and are thereby submitting their objection within the time-frame and accompanied with the relative deposit [vide **DOC 1**, based on the following grievances:

1. **<u>The product of the recommended bidder bears a CE marking and claims conformity with the Medical Devices Regulation to which it is not entitled</u>**

1.1 The Blue Medical Instrument Protector is placed on the market by its manufacturer as a CE-marked medical device.

1.2 It is the submission of the Appellants that an instrument protector is neither a medical device within the meaning of Article 2(1) of Regulation (EU) 2017/745 on medical devices (hereinafter the "MDR"), which definition is reproduced in the Glossary of the tender document itself, nor an accessory for a medical device within the meaning of Article 2(2) thereof.

1.3 An instrument protector is not intended to be used for human beings for any medical purpose, it does not itself clean, disinfect or sterilise any device, and it neither enables nor directly assists the medical functionality of any device. Its function, as described in Specification 1.1 of the tender document, is merely to "protect very fine, fragile and pointed instruments during CSSD reprocessing as well as during storage after sterilization".

1.4 It follows that the Blue Medical Instrument Protector falls outside the scope of the MDR, and cannot lawfully bear the CE marking or be accompanied by a claim of conformity with the MDR. In this respect, Article 30(3) of Regulation (EC) No 765/2008 is categorical:

> **"The CE marking shall be affixed only to products to which its affixing is provided for by specific Community harmonisation legislation, and shall not be affixed to any other product."**
>
> [added emphasis]

1.5 Furthermore, Article 7 of the MDR prohibits labelling and instructions for use which may mislead the user by "ascribing functions and properties to the device which the device does not have".

1.6 The product on offer was therefore presented in this tender on the strength of a regulatory status which it does not have. The Appellants reserve the right to elaborate further on this grievance during the hearing, including by way of technical evidence.

2. **<u>The offer of the recommended bidder cannot be compliant with the tender document</u>**

2.1 The tender document attaches distinct documentary requirements to products which fall under the MDR and to products which do not. Clause 2.3 of Section 3 requires, for medical devices, the submission of "a valid Declaration of Conformity for product being offered", whilst Clause 2.5 requires, for products falling outside the MDR, "a declaration [...] confirming the classification of the product". Clause 3.1.2 of Section 3 further requires that medical devices "must meet those standards established by European and/or Maltese legislation".

2.2 It is the submission of the Appellants that the recommended bidder cannot satisfy these requirements either way. If its product is presented as a medical device, its Declaration of Conformity and the related declarations in its Technical Offer Form are not valid, for the reasons set out under the first grievance. If, on the other hand, its product is not presented as a medical device, the declaration required by Clause 2.5 is lacking.

2.3 The Technical Offer Form is a Note 3 document, in respect of which no rectification is permitted. An invalid declaration of conformity or classification cannot be corrected at evaluation stage without the offer being altered in substance.

2.4 In view of the aforesaid, the offer of the recommended bidder is not "the cheapest priced offer satisfying the administrative and technical criteria" within the meaning of Clause 6.1 of the Instructions to Tenderers, and the recommendation for award in its favour cannot be sustained.

3. **Breach of Clause 3.2.1 of Section 3 and of the principle of self-limitation**

3.1 Clause 3.2.1 of Section 3 of the tender document provides that "**The Department shall accept the classification of the product being offered as determined by the competent authority in Malta.**" The classification of the product on offer is therefore not left to the self-declaration of the tenderer, nor to the discretion of the Evaluation Committee.

3.2 It is the submission of the Appellants that, in view of the matters raised under the first grievance, the Evaluation Committee could not accept the classification declared by the recommended bidder at face value, and rank its offer on the strength of it, without the determination contemplated by Clause 3.2.1.

3.3 In so doing, the Evaluation Committee departed from the rules which the Contracting Authority had set for itself, in breach of the principle of self-limitation and of the principles of equal treatment and transparency enshrined in Regulation 39 of the PPR. As held by the General Court of the European Union in Case T-415/10, *Nexans France v. European Joint Undertaking for ITER and the Development of Fusion Energy* (para. 80):

> "[...] where, in the context of a call for tenders, the contracting authority defines the conditions which it intends to impose on tenderers, **it places a limit on the exercise of its discretion and, moreover, cannot depart from the conditions which it has thus defined in regard to any of the tenderers without being in breach of the principle of equal treatment of candidates.**"
>
> [added emphasis]

3.4 The principle was applied by the Court of Appeal [Superior] in *Cherubino Limited v. Ministeru għall-Ambjent, l-Enerġija u l-Intrapriża et* (App. Ċiv. 139/23/1, decided on the 12th July 2023), where the Court held that:

> "[...] **mill-bidu nett, meta ssir dikjarazzjoni mill-oblaturi dwar il-materjal, dak dikjarat irid jiġi verifikat mas-sejħa.** [...] **Dan m'għandux iwassal għaċ-ċirkostanżi li l-orħos offerta tiġi magħżula senz'altru.**"
>
> [added emphasis]

3.5 Accordingly, the fact that the offer of the recommended bidder is the cheapest cannot, of itself, justify its selection where the regulatory status of the product on offer, and the declarations made in respect thereof, were not verified against the requirements of the tender document. Such an approach is, moreover, prejudicial to every economic operator, including the Appellants, who prepared and priced its offer in good faith on the basis of the requirements as published.

NOW, THEREFORE, whilst reserving the right to put forward any other submissions, the Appellants are hereby requesting this Honourable Board to:

i. **To order the defendants, or whosoever of them, to revoke the letter dated 5th October 2026 and cancel the recommended award to Drugsales Ltd;**

ii. **To order a fresh evaluation of the bids by a newly composed Evaluation Committee;**

iii. **To refund the deposit paid by the Appellants in its entirety; and**

iv. **To do anything else which is conducive and necessary for the proper execution of the above requests.**

Medina Healthcare Limited are hereby reserving their right to present further evidence and submissions, both orally and in writing, during the hearing. Additionally, Medina Healthcare Limited are hereby reserving the right to submit additional grievances, once the offer of the recommended bidder and the evaluation report are made available.

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Bank of Valletta p.l.c
Registration Number: C 2833
Registered Office: 58 Zachary Street, Valletta VLT 1130 - Malta

Pay third party

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Transaction details

Payer's name:	MEDINA HEALTHCARE LIMITED
Payee type:	Corporate Payee
Company name:	Cashier Malta Government
Relation:	Administrative Services
Reason:	Purchase of Services
Payment details:	CPSU5887 2
Currency:	EUR - Euro
Beneficiary IBAN/Account:	MT55MALT011000040001EURCMG5001H
Beneficiary IBAN/Account type:	Valid IBAN of country - Malta
Bank name:	Other bank
Bank address / Bank's BIC:	Let the bank apply the beneficiary bank BIC
Beneficiary address:	No
From account:	Overdraft (EUR) 4002316047 9
Charges should be paid by:	Shared - I pay BOV charges; pays the beneficiary bank charges
Amount:	EUR 400.00
BOV to transfer the money:	as soon as possible
Receiving bank to get the money as:	normal priority payment
FPAD Result:	We couldn't confirm that the name you entered matches the recipient's account. This might happen if the recipient's bank doesn't support name checks yet or if there's a temporary issue. Please double-check that the name and account details are correct before continuing. If any details are wrong, the payment could go to the wrong account or may be fraudulent and may not be recoverable. If you're confident everything is correct, you can go ahead and make the payment.
Saved template:	no

Additional information

Credit amount:	EUR 400.00
Debited amount (excluding charges):	EUR 400.00
Estimated amount to be withdrawn from account:	EUR 401.00
Transaction charge:	EUR 1.00

Transaction result

Status:	Your instructions have been processed successfully.
Transaction ID:	187027022