



The Public Contracts Review Board (info.pcrb@gov.mt)

Notre Dame Ditch
Floriana

15th June 2026

Letter of Objection of Drugsales Limited

Re: Appeal against Award Decision – Tender CPSU5245/26 –Supply of Disposable Temperature Probe Covers

Reference: CPSU5245/26 – Tender for the Supply of Disposable Temperature Probe Covers

Dear Sirs/Madams,

We write on behalf of Drugsales Limited (C-1780) of Ferreri Buildings, Idward Street, Ta' Qali National Park, Attard with reference the tender in subject.

By means a letter dated 5 June 2026, the contracting authority stated that the procurement was recommended for award to Europharma Ltd, being the cheapest priced offer satisfying the administrative and technical criteria.

We hereby submit this appeal against the award decision issued in relation to Tender CPSU5245/26. Our company is the supplier of the original Welch Allyn Electronic Thermometer probe cover referenced in the tender specifications, namely item code WA-05031-110.

The Contracting Authority specified under Section 3 – Specifications that:

“Equivalent probe covers should have identical performance as the original product.”
(Specification 2.3)

Compliance with the requirement of identical performance as the original product constituted a mandatory technical requirement and not merely a desirable characteristic.

Ground 1 – Lack of Demonstrable Evidence of Identical Performance, and Obligation of the Bidder to Provide such evidence at Tendering Stage

Information provided by the contracting authority shows product awarded is Suzhou ACE Biomedical A-ST-PC-25. The manufacturer's published literature describes the product as



compatible with Welch Allyn SureTemp thermometers and refers to features such as universal fit, prevention of cross-contamination, one-handed operation and latex-free construction.

However, literature available in public domain does not provide evidence demonstrating:

- identical performance to the original Welch Allyn probe cover;
- comparative clinical validation;
- comparative accuracy testing;
- equivalence studies;
- performance data demonstrating that temperature measurements obtained through the offered probe cover are identical to those obtained using the original product.

Compatibility and physical fit cannot automatically be equated with identical performance. The tender expressly required identical performance, which is a significantly higher standard than compatibility. Identical performance in this context could relate, amongst others, to characteristics such as -

- Rate of transfer of heat
- Thermal conductivity
- Thermal mass of the probe cover itself
- interaction or effect on the calibration and accuracy of the temperature probe itself
- variation between samples in the above parameters.

In terms of the General Conditions Governing Tenders (as well as according to jurisprudence and established principles of procurement):

*5.6 Where in the tender document a standard, brand or label is quoted, it is to be understood that the Contracting Authority will accept equivalent standards, brands or labels. However, **it will be the responsibility of the respective bidders, at tendering stage, to prove that the standards, brands or labels they quoted are equivalent to the standards, brands or labels requested by the Contracting Authority.***

Given that the bidder submitted a bid with an allegedly “equivalent” probe to the original, it was incumbent on the said bidder to provide concrete evidence that the “equivalent” probe offers an **identical** performance to the original product, as requested in the same tender specifications.



The bidder therefore had the obligation to bring sufficient and reliable scientific evidence to show that the “equivalent” product effectively gives identical performance to the original product, and this in a consistent manner and in the several conditions and various patients for which the probe is used.

A simple declaration by the bidder or ‘ticking of the box’ is not sufficient proof of equivalence.

Failing production of such evidence of identical performance by the bidder at tendering stage, the offer had to be rejected by the contracting authority.

Ground 2 – Insufficient Sample Evaluation to Establish Identical Performance

Without prejudice to the above, the tender documentation provided that samples may be requested during evaluation and specified that only ten (10) samples would be requested.

The estimated quantity under the contract is approximately 4.18 million probe covers over the contract period.

The Appellant respectfully submits that an evaluation based on ten samples cannot reasonably establish that a product intended for supply in quantities exceeding four million units possesses “identical performance” to the original product across all manufactured batches and in all conditions. Especially in consideration of all the relevant performance characteristics involved in ensuring that the thermometers and probes continue to provide validated, accurate and repeatable readings.

In particular, evaluation of ten samples may demonstrate:

- physical fit;
- ease of use;
- compatibility with the thermometer;
- packaging characteristics.

However, such evaluation cannot by itself scientifically demonstrate:

- identical thermal transmission characteristics;
- identical measurement accuracy;
- identical repeatability;
- identical performance consistency across mass production batches;
- absence of clinically significant variation.



Unless the contracting authority carried out documented comparative performance testing against the original Welch Allyn probe cover, the Appellant submits that there was no objective basis upon which compliance with Specification 2.3 could be conclusively established.

Furthermore, it is to be noted that the requesting of and testing of any samples by the contracting authority does not and cannot in any way remedy a deficiency by the bidder to submit its own proof of equivalence and identical performance.

It is the bidder who has the obligation and responsibility to provide such evidence of equivalence, which evidence must be provided in all cases upon submission of the bid.

A request for samples by the contracting authority is merely an additional check that may be done by the contracting authority, which can not in any do away with or substitute the obligation of the bidder to provide proof of equivalence.

Ground 3 – Breach of Transparency and Equal Treatment Principles

Article 18 of Directive 2014/24/EU requires contracting authorities to treat economic operators equally and without discrimination and to act in a transparent and proportionate manner.

Regulation 18 of the Public Procurement Regulations (S.L. 601.03), transposing Directive 2014/24/EU into Maltese law, incorporates the same fundamental principles.

Where a mandatory specification requires “identical performance”, *all tenderers must be assessed against the same objective and verifiable standard.*

If compliance with the requirement was accepted without documented evidence establishing identical performance, this would constitute unequal treatment and a manifest error in the technical evaluation process.

Ground 4 – Clinical Importance of Accurate Temperature Measurement

Temperature monitoring is a clinically significant diagnostic parameter. Particular concern arises in vulnerable patient populations, including:

- neonates;
- immunocompromised patients;
- oncology patients;
- intensive care patients;



- elderly patients.

Even small measurement variations may influence clinical decision-making, escalation pathways, infection screening protocols and treatment interventions.

For this reason, the tender did not merely require compatibility but expressly required “identical performance as the original product”.

The Appellant submits that the Evaluation Committee was required to possess objective and documented evidence demonstrating that the awarded product satisfies this mandatory requirement before determining technical compliance. Typically such evaluations are carried out by independent, suitably qualified and certified laboratories, and not by a simple in use evaluation on 10 samples.

Ground 5 – Manufacturer's Instructions for Use Explicitly Warn Against Use of Non-OEM Probe Covers

The Appellant further submits that the original manufacturer of the Welch Allyn SureTemp thermometer expressly warns users regarding the use of non-original probe covers.

Page 10 of the Welch Allyn Instructions for Use (IFU) states:

"WARNING: Use only Hillrom probe covers. The use of other manufacturer's probe covers or no probe cover may produce temperature measurement errors and/or inaccuracy."

This warning was issued by the original manufacturer of the thermometer and reflects the manufacturer's assessment that probe cover design, material composition, thickness, thermal transfer characteristics and dimensional tolerances may influence temperature measurement performance.

The warning is particularly relevant in the present procurement because the tender specification did not merely require physical compatibility but specifically required that:

"Equivalent probe covers should have identical performance as the original product."

The existence of the manufacturer's warning demonstrates that identical performance cannot be presumed solely because a probe cover physically fits the thermometer.

Rather, the warning confirms that the use of third-party probe covers may result in measurement errors or inaccuracies unless equivalence has been objectively established through appropriate validation and testing.



In these circumstances, the Appellant respectfully submits that the Evaluation Committee should have possessed robust and documented evidence demonstrating that the awarded third-party probe cover achieves identical performance to the original Hillrom/Welch Allyn probe cover notwithstanding the manufacturer's explicit warning.

Absent such evidence, the conclusion that the awarded product complies with Specification 2.3 appears unsupported and contrary to the precautionary approach required for medical devices used in patient diagnosis and monitoring.

The concern is particularly significant in vulnerable patient populations, including neonates, oncology patients, immunocompromised patients, intensive care patients and elderly patients, where even small temperature measurement deviations may affect clinical assessment, escalation pathways and treatment decisions.

Request for Relief

The Appellant respectfully requests that the Public Contracts Review Board:

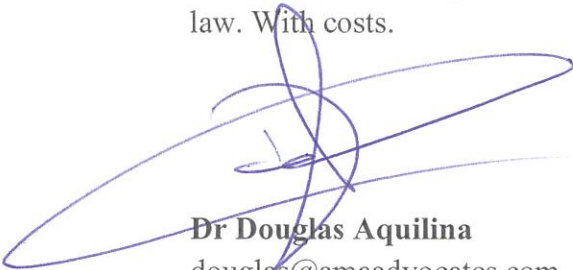
1. Obtain and review the complete technical evaluation report and all documents relied upon by the Evaluation Committee in concluding that the awarded product demonstrated “identical performance” to the original Welch Allyn probe cover.
2. Verify whether any independent lab comparative performance validation, laboratory testing, clinical testing, equivalence study or manufacturer certification was submitted and evaluated.
3. Determine whether the bidder submitted sufficient objective evidence to prove equivalent “identical performance” in compliance with Specification 2.3.
4. Annul the award decision and declare non-compliance of the offer submitted by Europharma Ltd, should it be determined that compliance with the mandatory requirement of identical performance was not objectively demonstrated, and
5. Should the award be annulled, give such orders in the circumstances including to order that the tender process is re-opened and re-evaluated, including such orders to ensure evaluation of other bids offering non original Welch Allyn are all checked for identical performance criterion as described above.
6. Refund appeal money paid.

The Appellant reserves the right to submit further observations following disclosure of the evaluation documentation relied upon by the Contracting Authority.



ATTARD MONTALTO & AQUILINA
ADVOCATES

Saving any other objections at the opportune stage, and reserving all rights and remedies at law. With costs.



Dr Douglas Aquilina
douglas@amaadvocates.com



Dr Mark Attard Montalto
mark@amaadvocates.com



Dr Samira Briffa
samira@amaadvocates.com

Public Contracts Review Board
Objection Receipt
Temporary Receipt for ~~Transcripts at €4 per page~~

Date: 15/06/2026

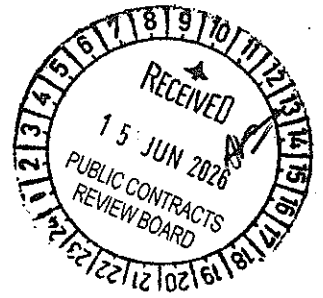
Received from: Drugsales Ltd

the sum of: 690 no of pages: 1

In respect of Tender: CPSU 5245/26

Cash: /Cheque No: 018094

Validity of receipt is subject to bank clearance, when payment is made by cheque.



Signature [Signature]

BOV
Bank of Valletta LABOUR AVENUE, NAXXAR, NXR9020

22-633
Date: 15/06/2026

Pay Ministry for Finance only
Six hundred and ninety
euros only € 690.00

Bank of Valletta p.l.c. Malta
DRUGSALES LIMITED A/C
NBC

[Signature]
Please do not write or mark below this line.

⑈018094⑈ 220633⑈ 16311330026⑈