

# **PUBLIC CONTRACTS REVIEW BOARD**

## **Case 2133 – Cft009-3188/25 (CPSU 2622/24) – Tender for the Supply of UV-C High Level Disinfection Machine for Flexible scopes**

**21<sup>st</sup> July 2025**

The Board,

Having noted the letter of objection filed by Dr Kristen Camilleri and Dr Jonathan Abela Fiorentino on behalf of Mamo TCV Advocates acting for and on behalf of Technoline Limited, (hereinafter referred to as the appellant) filed on the 30<sup>th</sup> May 2025;

Having also noted the joint 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 9<sup>th</sup> June 2025;

Having heard and evaluated the testimony of the witness Mr Evert Alink (Representative of UV Smart Technologies) as summoned by Dr Jonathan Abela Fiorentino acting for Technoline Limited;

Having heard and evaluated the testimony of the witness Mr Remmie Micallef (Member of the Evaluation Committee) as summoned by Dr Jonathan Abela Fiorentino acting for Technoline Limited;

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 14<sup>th</sup> July 2025 hereunder-reproduced.

### **Minutes**

#### **Case 2133 Cft009-3188/25/CPSU2622/24 – Tender for the Supply of UV-C High Level Disinfection Machine for Flexible Scopes.**

The tender was issued on the 28<sup>th</sup> of February 2025, and the closing date was the 4<sup>th</sup> of April 2025.

The estimated value of the tender, excluding VAT, was €110,169.00

On 30<sup>th</sup> May 2025, Technoline Limited. (MT1027-1312) lodged an appeal against Central Procurement and Supplies Unit – the Contracting Authority, in accordance with Regulation 270 of the Public Procurement Regulations. The appellant's bid was rejected; the tender being awarded to a cheaper compliant offer.

A deposit of €400.00 was paid.

There were Two bids.

On the 14<sup>th</sup> of July 2025, the Public Contracts Review Board (PCRB), composed of Mr. Kenneth Swain as Chairman, Mr Lawrence Ancilleri, and Mr. Keith Victor Grech as members, convened a public hearing to consider the appeal.

The attendance for this public hearing was as follows:

**Appellant: Technoline Limited. (MT1027-1312)**

- Dr. Jonathan Abela Fiorentino – Legal Representative
- Dr. Joseph Camilleri – Legal Representative
- Dr. Kirsten Camilleri – Legal Representative
- Mr. Nicholas Sammut – Company Legal Representative
- Mr. Mario Gatt – Company Representative
- Mr. Alan Mizzi – Company representative
- Mr. Evert Alink – Company representative
- Ms. Gabrielle Camilleri – Student.

**Contracting Authority: Central Procurement and Supplies Limited.**

- Dr Alexia J Farrugia Zrinzo – Legal Representative.
- Dr Leon Camilleri – Legal Representative.
- Ms. Kirsty Agius – Chairperson.
- Mr. Anton Marmara -- Evaluator
- Mr. Remmie Micallef – Evaluator
- Mr. Patrick Pace -- Evaluator
- Ms. Branica Amato Gauci – Company Representative

**Recommended Bidder: E.J.Busuttil Limited. (MT1098-1209)**

- Mr. Neil Bugeja – Company Representative

**Opening Statements**

Dr Kenneth Swain, Chairman of the Public Contracts Review Board, welcomed the parties present: the appellant *Technoline Limited*, the Contracting Authority *Central Procurement and Supplies Unit (CPSU)*, and the representative of the recommended bidder, *E.J. Busuttil Ltd.*

He invited the appellant's legal representative, Dr Jonathan Abela Fiorentino, to proceed with his initial submissions.

**Initial Submissions**

*Initial Submissions by the Appellant*

Dr Abela Fiorentino opened by stating that the appeal was of a technical nature, focusing on three main objections:

1. Compatibility with ENT Scopes

The awarded product, as per its documentation, is intended for the disinfection of ultrasound probes and not ENT (Ear, Nose, Throat) endoscopes. Since the product is to be used at the ENT outpatient department of Mater Dei Hospital—where Karl Storz brand endoscopes are used—the awarded product is incompatible.

## 2. Data Storage and Tamper-Proofing

The awarded system does not store disinfection data on the device itself. Instead, data is saved externally, rendering it vulnerable to tampering and inconsistent with the tender's requirement for tamper-proof internal storage.

## 3. Certification and Legal Compliance

The awarded product lacks appropriate certification:

- It is not registered with the EUDAMED database.
- It does not comply with the EU Medical Device Regulation (MDR).
- It lacks a Unique Device Identifier (UDI) and an SRE (Safety and Regulatory Evidence) certificate.

*Initial Submissions by the Contracting Authority.*

Dr Camilleri, representing Central procurement and Supplies Unit (CPSU), argued that all the appellant's claims had already been addressed. The product was evaluated and recommended strictly according to the tender criteria.

### **Witness.**

*Mr Evert Alink (137067550BSN) Summoned by Dr Jonathan Abela Fiorentino*

Mr. Evert Alink identified himself as the Head of Commerce, with UV Smart Technologies of Netherlands, and Technoline is the seller in Malta. He referred to Point no. 1 Design and Validated for Ent endoscopes. The label clearly states UVC disinfection chamber for Ultrasound probe, and it was not designed for ENT endoscopes. The declaration of conformity was not sent at all.

**Tamper Proof Data – Collected and Stored on the Device.**

The tender required that disinfection data be collected and stored on the device in a tamper-proof format, and downloadable from the unit itself. The awarded product relies on a separate software (Germitrac) to access disinfection logs. The data can be tampered with, as they can be filtered and downloaded as a csv file which is a format for Excel and an Excel can be easily tampered with.

It is recommended that data be backed up daily. It is also recommended that a security backup be performed to transfer data to another drive. Germitic may not, under any circumstances, be held responsible for the loss of data stored in the equipment.

Dr Abela Fiorentino asked the witness, how he could conclude that the product that won the tender, was not compliant.

Mr. Alink explained that the intended use does not include ENT endoscopes. It is not designed to do it. The device disinfects video scopes, and the cable has to be put on top, where it is not a disinfection chamber.

Referring to 6.2.3 the tender says that it needs to be MDD certified but it was replaced by MDR in 2017. It is strange to use a defuncted law for a tender. As of September 2024, the MDD has ceased to be enforced, and any product sold must have valid article 120 of MDR. The product that was offered did not have a valid SRE certificate. Even if it is awarded, it cannot be installed anymore, as the date to be put into service closed on the 27<sup>th</sup> of May 2025. One can only sell this product if there is a transition plan in place, with a manufacture declaration template.

There are only two who are in this field.

Referring to 6.3.4 Comply with MDD and other relevant EU Legislation. MDR Legal Framework and Transition Deadlines.

Regulation (EU) 2017/745 (Medical Device Regulation, or MDR) replaced the Medical Device Directive (93/42/EEC, MDD).

A grace period (Article 120) allowed MDD-certified devices to remain on the market until the earlier of their certificate expiry or 26 May 2024, which was later extended to 26 September 2024. To be eligible for this grace letter you needed to have:

A valid MDD certificate issued before 26May 2021.

Not made significant changes to the device since 2011.

Lodged a formal application for conformity assessment by a Notified Body.

Received a confirmation of the formal application acceptance by a Notified Body.

Article 120(3c) a written agreement must have been signed no later than 26 September 2024. But the French manufacturer had no intention to put this device in the MDR.

So, with no EU med registration, no public declaration, no notified body grace period letter, this bid should never have been offered.

Directive 2014/24/EU, article 18.

‘Contracting authorities shall treat economic operators equally and without discrimination and shall act in a transparent and proportionate manner’.

Regarding Equal Treatment, we invested in MDR complaints, and to accept a product that has been in the market for two months would be highly discriminatory.

For Transparency, the authority neither verified AE1’s legal market status nor its data-logging shortfall, so the evaluation criteria were not applied transparently.

For proportionality, ignoring a hard legal cutoff (26Sept 2024) is a disproportionate, illegal relaxation of the rules for one bidder, it distorts competition and procurement value.

Dr Abela Fiorentino remarked that 2.9 stipulates that the UVC must incorporate a system that records and stores information about each decontamination cycle.

Mr. Alink emphasised that incorporate means that the information is stored and seeable on the device. Regarding the Antigel mix AE1, the product is not being marketed anymore, as it was intended to be used for TOE probes, an ultrasound used to check the heart.

#### **Cross-Examination by Dr Leon Camilleri**

- Mr Alink clarified that he has 10 years of experience in medical devices but holds a business background, not a technical one. He works for UV Smart.
- He acknowledged he was not involved in E.J. Busuttil's submission. He assisted to fill in the technical offer with Technoline.

#### **Re-Examination by Dr Jonathan Abela Fiorentino**

- Mr Alink explained there are only two market players in this niche, and based on the documentation, the awarded product must be the one from the French competitor—not UV Smart.

#### **Witness:**

*Mr Remmie Micallef (ID 539274M) Summoned by Dr Jonathan Abela Fiorentino.*

- Role: Biomedical technician and Principal Technical Officer with 30 years' experience.
- Evaluation Process:
  - Committee included Mr Micallef, Mr Anton Marmara, and Mr Patrick Pace.
  - Decision was based on documentation provided by E.J. Busuttil, including the operator's manual.
  - The manual indicated that the product is suitable for both ultrasound and ENT scopes without operating channels.
- Data Logging:
  - Data is stored within the Antigermix AE1 system and accessed using Germitrac software.
  - A dedicated printer issues a chit confirming successful disinfection (Clause 3.4, Page 10 of manual).
  - Although a PC is needed to view data, the internal system matches the downloadable data, preventing tampering.
- Disclaimer:

Dr Abela Fiorentino referred to disclaimer, which recommends that the data be backed up daily. It is also recommended that a security backup be performed to transfer data to another drive. Germitec may not, under any circumstances, be held responsible for the loss of data stored in the equipment.

Mr. Micallef stated that every apparatus has a similar disclaimer regarding data. The data is tamper proof as the data can only be downloaded with a certain software, with no access to vary data on the screen.

*Cross-Examination by Dr Leon Camilleri*

The witness is a biomedical technician and Principal Technical officer for 30 years. Confirmed that the manual refers to the Antigermix AE1 system supplied by E.J. Busuttil.

**Final Submissions**

*Final Submissions by Dr Jonathan Abela Fiorentino (Appellant)*

- Emphasised the non-compliance of the awarded product:
  - Data must be stored within the device and tamper-proof; this is not guaranteed.
  - The product lacks MDR certification and has surpassed its legal date of usage under EU law.
- There was the need of a transition certification, for this product to be valid after the Regulation Date, and this was never submitted. This product could not be sold or used after May 27<sup>th</sup> according to EU law.

*Final Submissions by Dr Leon Camilleri (CPSU)*

- Asserted that no valid proof was provided by the appellant:
  - Appellant's witness was not a technical expert but a qualified business developer and had no direct knowledge of the awarded bid.
  - CPSU's witness is an experienced technician with 30 years of experience, who confirmed the product's technical compliance.
  - The software-based storage meets tender requirements and offers sufficient data integrity.
  - No verifiable evidence was presented to support the lack of registration or certification issues.

**Conclusion of the Hearing**

With no further arguments, Mr Kenneth Swain thanked all parties and formally concluded the session.

End of Minutes

---

**Hereby resolves:**

The Board refers to the minutes of the Board sitting of the 14<sup>th</sup> July 2025.

Having noted the objection filed by Technoline Limited (hereinafter referred to as the Appellant) on 30<sup>th</sup> May 2025, refers to the claims made by the same Appellant with regard to the tender of reference CfT009-3188/25 (CPSU 2622/24) listed as case No. 2133 in the records of the Public Contracts Review Board.

Appearing for the Appellant:

Dr Kristen Camilleri & Dr Jonathan Abela Fiorentino

Whereby, the Appellant contends that:

a) ***Lack of Validation for the intended scope of use (ENT Channel-less scope)***

Clause 1.0 of the tender dossier clearly states: *“This tender covers the outright purchase and maintenance of a system incorporating an Ultra-Violet C (UV-C) Emitting Machine specifically designed and validated to provide terminal disinfection of flexible and Rigid Scopes, so as to inactivate possible bacterial contamination, after manual cleaning.”*

In line with this requirement, the Appellant submitted the 'D60 UV-C' machine, a system specifically designed for UV disinfection of ENT endoscopes and other channel-less scopes. Its intended use aligns directly with the scopes of the tender - namely, disinfection of flexible and rigid scopes, including those used in ENT outpatients settings. Conversely, the machine proposed by the winning bidder, the 'Anti Germix AEI', is not validated for this purpose. The official documentation and physical labelling affixed to a currently operational Anti Germix explicitly reference its use for disinfection of ultrasound probes, not ENT scopes. The absence of any reference to ENT scopes is not a mere oversight. It reflects the fact that the machine is not designed or validated for such use. This is not a trivial discrepancy. ENT endoscopes, particularly channel-less models, require a machine validated for their specific disinfection needs. The use of a non-compliant disinfection system introduces a risk that the terminal disinfection process may be ineffective or not adequately validated, defeating the entire objective of the tender. Furthermore, the Appellant notes that the ENT Outpatients Department at Mater Dei uses Karl Storz endoscopes. According to Karl Storz official disinfection manual, the only UV-C system explicitly recognised and validated for use with their endoscopes is UV Smart. The Anti Germix AEI is not listed as a compatible or validated system by Karl Storz. This is a critical point: where specific medical equipment is in use, the disinfection system must be officially validated for that equipment. The selected machine fails this threshold. This strongly suggests that the selected machine does not meet the tender's technical specifications, either by design or by validation. The awarding of the tender to a bidder proposing a machine with such clear shortcomings amounts to a breach of the fundamental principles of equal treatment and transparency, and undermines the integrity of the procurement process.

b) ***Non-compliance with Data Storage and Tamper-Proofing Requirements***

Clause 2.9 of the tender dossier expressly requires that: *“The UV-C must incorporate a system that records and stores information about each decontamination cycle undertaken; the data collected should include the time, date and cycle duration. This data capture mechanism must be tamper proof. The stored data should then be downloadable onto a computer using Microsoft Windows 10 operating system.”* The Appellant's proposed machine, the D60 UV-C, fully satisfies this requirement. It stores track-and-trace data internally, and this data

cannot be accessed externally or manipulated, except by trained-service personnel. This built-in limitation renders the data storage system tamper-proof, in line with the tender's explicit requirement. By contrast, the selected machine, the Germitec Anti Germix AE1, does not store decontamination data internally. Instead, data is stored on a separate, external computer. Such a setup is inherently vulnerable, as the external computer can be disconnected, removed, or interfered with. This fails the tamper-proofing requirement and poses a significant risk to traceability and audit reliability - both of which are critical in a clinical disinfection context.

c) ***Lack of Registration in the EUDAMED Database***

Clause 6.2.3 of the tender dossier requires: "*A 'declaration of conformity' from the parent company*"

The Anti Germix AE1 system proposed by the awarded bidder is not listed in the EUDAMED database, meaning it is not registered under the Medical Device Directive (MDD) or the Medical Device Regulation (MDR). Only one Germitec device, the 'Chronos, appears in EUDAMED, and it is not intended for use with ENT scopes. This omission was not done by mistake. It confirms that the Antigermix AE1 is not officially recognised as a compliant medical device within the EU framework for the purposes intended in this tender. In contrast, the Appellant's proposed machine, the D60 UV-C (UV Smart), is duly registered in EUDAMED, and thus compliant.

d) ***Failure to Comply with EU Medical Device Certification Requirements***

Clause 6.3.4 of the tender dossier states: "*Equipment offered shall comply with the applicable medical devices directive and any other relevant E.U. legislation. To be supported by 'Declarations of Conformity. A copy of the certificate shall be submitted at tender stage.'*"

The Antigermix AE1 machine does not possess a Unique Device Identifier (UDI), which is a core component of the MDR framework and required for traceability and compliance across the EU. Without a UDI, the device cannot be considered validly certified under EU law, nor does it meet the minimum documentation and conformity requirements outlined in the tender. In contrast, the Appellant's proposed device is certified and holds a valid UDI, fully satisfying both the letter and spirit of the clause.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 9<sup>th</sup> June 2025 and its verbal submission during the hearing held on 14<sup>th</sup> July 2025, in that:

a) ***On the First Ground of Appeal - Lack of Validation for the Intended Scope of Use (ENT Channel-less scope)***

The objector in the first part of this grievance states that the machine offered by the Objector is not validated for its intended scop, that is, according to the objector, to disinfect the ENT endoscopes. The evaluation committee had conducted a thorough evaluation process and confirmed that the product offered by the recommended bidder was suitable for all its intended uses. The Tender documents mention ENT only in clause 3.1 of the technical specifications which states that. "*All accessories to accommodate the flexible scopes used at the ENT Out Patient Department*" The

product recommended for award states in its literature that the unit is suitable for ENT scopes that do not have operator channels. It is thus evident and clear that the offered product is compliant and fulfils the intended use cited by the objector. Moreover, the fact that Mater Dei Hospital currently does not use the brand offered by the recommended bidder in the ENT Department does not mean that this is not suitable for the hospital's use. This Honourable Board certainly understands that a brand will not recommend the use of product of a different brand if it manufactures such product, however this certainly does not mean that a product from a different brand is not suitable! Without prejudice to the above, the tender document did not even require any compatibility with any Karl Storz ENT equipment!

b) ***On the Second Ground of Appeal - Non-Compliance with Data Storage and Tempering Proofing Requirements***

In this part of the objection, the objector argues that the product offered by the recommended bidder is not compliant to clause 2.9 of the tender dossier, which states that: The UV-C must incorporate a system that records and stores information about each decontamination cycle undertaken; the data collected should include the time, date and cycle duration. This data capture mechanism must be tamper proof. The stored data should then be downloadable onto a computer using Microsoft Windows 10 operating system. The product offered by the recommended bidder does include a system that records and stores information. The literature of the recommended product explains that all tracking data are stored within the Antigermix E1 system. "This data can be accessed via the Germitra software, which will also be provided. There was thus no reason for the evaluation committee to find any non-compliance to clause 2.9, above cites and for the above reasons this third grievance ought to be rejected.

c) ***On the Third Ground of Appeal - Lack of Registration in the EUDAMED Database.***

The objector states or implies that the offer of the recommended bidder is not compliant since the offered product is not listed in the EUDAMED and according to the objector this means that the product is not registered under the Medical Devices Directive or the Medical Devices Regulation. CPSU respectfully submit that such registration is not a tender requirement and moreover, it is still not a mandatory registration under BU Law.

d) ***On the Fourth Grievance - Failure to Comply with EU Medical Device Certification Requirements***

The Objector states that the product offered by the recommended bidder is not compliant to clause 6.3.4 of the tender dossier because it does not have a Unique Device Identifier. This clause states that: Equipment offered shall comply with the applicable medical devices directive and any other relevant E.U. legislation. To be supported by 'Declarations of Conformity. A copy of the certificate shall be submitted at tender stage. CPSU humbly submits that the above cited clause does not make any reference to the Unique Device Identifier and neither does any clause in the tender document. The relevant clause only states that EU legislation compliance must be proven by a declaration of

conformity. The recommended bidder did submit a declaration of conformity and thus it sufficed the relevant tender criteria. The evaluation committee is bound by the principle of self-limitation in both what it can request and in what it can consider and the evaluation process had to be done by comparing the offer presented to the requirements in the tender document. Since the offer of the recommended document were all fulfilled by the objector, the evaluation committee could only recommend such offer for award as otherwise it would have been acting ultra vires and in breach of the principle of self-limitation.

This Board, after having examined the relevant documentation to this appeal and heard submissions made by all the interested parties including the testimony of the witnesses duly summoned, will now consider Appellant's grievances.

a) **On the First Ground of Appeal – Lack of Validation for the Intended Scope of Use (ENT Channel-less scopes):**

The Board is satisfied that the Evaluation Committee acted within its remit in determining the technical compliance of the awarded product with the tender specifications. The product offered by the recommended bidder, as per the submitted documentation, is explicitly described as suitable for the disinfection of ENT scopes that do not include operator channels. The reference to "ENT" in the tender dossier is confined to Clause 3.1 of the technical specifications and does not stipulate any obligation for compatibility with a specific brand or model, such as Karl Storz. Therefore, the Appellant's insistence on validation according to a particular manufacturer's standards is not grounded in the requirements of the tender documentation. Moreover, the principle of equal treatment requires that all bids be evaluated strictly on the basis of the published criteria; the introduction of additional brand-specific compatibility conditions at appeal stage would violate this principle.

b) **On the Second Ground of Appeal – Alleged Non-Compliance with Data Storage and Tamper-Proofing Requirements:**

The Board finds no merit in the argument that the awarded product fails to comply with Clause 2.9 of the tender dossier. The documentation submitted by the recommended bidder clearly states that disinfection cycle data is stored within the Antigermix AE1 system and is accessed through the proprietary Germitrac software. The evidence presented by the Contracting Authority—particularly the operator's manual and the testimony of its experienced technical officer—confirms that the system includes a secure internal data logging mechanism and that the data can be retrieved in a manner consistent with the requirements of Clause 2.9. The Appellant's concerns regarding the potential for tampering are speculative and were not substantiated by verifiable evidence. In this regard, the Board reiterates that general disclaimers included in technical manuals do not, on

their own, invalidate compliance where the fundamental functionality meets the tender's requirements.

c) **On the Third and Fourth Grounds of Appeal – EUDAMED Registration and MDR Certification:**

The Appellant's contention that the awarded product lacks appropriate certification under EU law is also not upheld. First, the Board notes that registration in the EUDAMED database is not a mandatory requirement under current EU regulations, nor was it specified as a requirement in the tender dossier. Second, Clause 6.3.4 of the tender requires that offered equipment complies with applicable EU legislation and be supported by a valid Declaration of Conformity. The recommended bidder submitted the requisite Declaration of Conformity, and no evidence was produced to show that this was invalid or non-compliant. The inclusion or absence of a Unique Device Identifier (UDI), while relevant under MDR, was not explicitly required in the tender specifications and therefore cannot be retroactively imposed as a condition. The Evaluation Committee was bound by the principle of self-limitation and acted correctly in assessing compliance based solely on the published requirements.

In light of the above, the Board finds that the evaluation process conducted by the Contracting Authority was both lawful and procedurally sound. The Appellant's objections introduce new interpretations and requirements that exceed those explicitly included in the tender documentation and are therefore unfounded.

**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