PUBLIC CONTRACTS REVIEW BOARD

07th October, 2025

Appeal Reference Number	**2141**
Tender Reference Number	**CT2057/2025**
Tender Name	**"Tender for the Leasing of Sixty-Six (66) Operational Brand – New Haemodialysis Machines with Reduced Environmental Impact on a Pay Per Use Basis to Mater Dei Hospital, St Vincent De Paul & Gozo General Hospital"**

The Public Contracts Review Board (hereinafter the 'Board' or the 'PCRB') convened a public hearing on the 26th August, 2025 to hear the appeal as filed by the appellant Medina HealthCare Limited (hereinafter the 'Appellant') on the 27th June, 2025, and after taking cognisance of:

The tender document for the 'Tender for the Leasing of Sixty-Six (66) Operational Brand – New Haemodialysis Machines with Reduced Environmental Impact on a Pay Per Use Basis to Mater Dei Hospital, St Vincent De Paul & Gozo General Hospital.' (hereinafter referred to as the "Tender Document");

The minutes of the proceedings dated 26th August, 2025 which are being reproduced hereunder:

> ***"PUBLIC CONTRACTS REVIEW BOARD***
>
> *Case 2141 Call for Remedies – CT2057/2025 – Tender for the Leasing of Sixty-Six (66) Operational Brand – New Haemodialysis Machines with Reduced Environmental Impact on a Pay Per Use Basis to Mater Dei Hospital, St Vincent De Paul & Gozo General Hospital.*
>
> *The tender was issued on the 17th of April 2025, and the closing date was the 6th of August 2025.*
>
> *The estimated value of the tender, excluding VAT, was €28,322,034*
>
> *On 27th June 2025, Medina Healthcare Limited lodged an appeal against Central procurement and Supplies Unit – the Contracting Authority, in accordance with Regulation 262 of the Public Procurement Regulations. The appellant felt aggrieved and filed this application, alleging breach of regulation 262.*
>
> *A deposit of €50,000 was paid.*
>
> *On the 26th of August 2025, the Public Contracts Review Board (PCRB), composed of Dr Ana Thomas as Chairperson, Mr. Keith Victor Grech and Mr. Lawrence Ancilleri, as members, convened a public hearing to consider the appeal.*

The attendance for this public hearing was as follows:

Appellant – Medina Healthcare Ltd. (C44038).
Dr Matthew Paris – Legal Representative.
Dr Zack Esmail - Legal Representative.
Mr. John Soler - Company Representative.
Ing. Vincent Micallef – Company Representative.

Contracting Authority – Central procurement and Supplies Unit (MFH).
Dr Alexia J Farrugia Zrinzo – Legal Representative.
Ing. Chris Attard Montalto – Representative.

Contracting Authority.
Dr Audrey Marlene Buttigieg Vella.

Interested Parties.
Mr Raymond Vella –A.M Mangion Ltd
Mr. Shuang Zhang – B. Braun Avitum AG.
Mr. Adriano Spiteri—Legal Officer.

Opening Statements

Dr Ana Thomas, Chairperson of the Public Contracts Review Board (PCRB), welcomed the parties present: the Appellant, Medina HealthCare Ltd.; and the Contracting Authority, the Central Procurement and Supplies Unit (CPSU).

Initial Submissions

Initial Submissions by the Appellant

Dr Matthew Paris began by stating that Medina HealthCare Ltd., together with another entity, required clarification on several ambiguities in the Tender Document. He argued that changes were necessary for the Tender to be implemented properly.

The first objection concerned the failure to divide the Tender into lots. Other concerns related to the contract's duration, eligibility requirements, and technical specifications.

According to Dr Paris, despite the issuance of clarification notes, ambiguities remained. These needed to be addressed either through further clarifications ordered by the PCRB or by cancelling the Tender entirely and issuing a new one that resolved all outstanding issues.

Initial Submissions by the Contracting Authority

Dr Alexia J. Farrugia Zrinzo responded with a preliminary submission. She argued that Medina had failed to indicate the legal basis for its remedy under sub-article 262, despite CPSU's earlier reply.

On the first grievance — that the Tender was not divided into lots — CPSU maintained that splitting was unnecessary, since the procurement concerned large quantities of the same product.

On the second grievance — alleged ambiguity — she noted that CPSU had issued several clarification notes in response to bidders' questions.

On the third grievance — technical clarifications — she argued these had been duly addressed within the required timeframe.

Witness:

Mr Chris Attard Montalto (ID No. 260567M) *– Summoned by Dr Paris Ing. Attard Montalto, Director of Medical Equipment at Mater Dei Hospital and other entities under the Ministry of Health, testified.*

He had drafted the requirements and specifications for this Tender, following discussions with doctors and nurses. A similar tender was issued in 2014 but only for Mater Dei Hospital. At the time, Gozo Hospital was managed by Steward Health Care, and Renal units existed only in Mater Dei and Gozo.

This Tender, however, covered haemodialysis machines for three sites: Mater Dei, Gozo Hospital, and St Vincent de Paul Residence (SVPR). The aim was to provide a standardised, homogeneous service across the Ministry.

Dr Paris quoted from Page 43.1 of the Tender Document:

"This tender is not divided into lots, and tenders must be for the whole quantities indicated. Tenders will not be accepted for incomplete quantities. Tender is not divided into lots since items in this tender are interlinked and the Contracting Authority requires the involvement of one contractor rather than multiple contractors to ensure that treatment, cooperation, operation of machines and training requirements are cohesive."

Ing. Attard Montalto explained that renal patients required treatment three to four times a week. Patients in Gozo should be able to use the same service at Gozo Hospital, which required identical machines across sites. For the past 12 years, Mater Dei and Gozo hospitals had used different machines.

Standardisation would make operations easier for doctors and nurses, avoid multiple training requirements, and allow centralisation and networking of the system across all three hospitals.

When asked by the Chairperson whether patients had ever been endangered by the use of different machines, Ing. Attard Montalto replied to ***no****.*

When questioned by Dr Paris on staff training obligations, he replied that contractors were obliged to train staff on the supplied machines. From a management perspective, one contract was preferable to multiple.

Dr Paris asked what would happen if the system failed, given patients' vulnerability. Ing. Attard Montalto explained that all machines had to be MDR (Medical Device Regulation) certified, which guaranteed reliability, and that manufacturer support was always available. It was unlikely all machines would fail simultaneously. However, he conceded that Malta and Gozo would indeed be dependent on one type of machine, and in the event of a recall, the service could be disrupted nationwide.

Cross-Examination by Dr Farrugia Zrinzo

She emphasised that MDR certification gave confidence in product safety.

Witness:

Ing. Vincent Micallef (ID No. 00343687M), *summoned by Dr Paris.*

Ing. Micallef is a Biomedical IT Engineer, an MDR person for twenty years, and an Environmental IT Engineer in a private hospital. He is the Technical Service IT Manager for Medina Healthcare.

He has been involved in this Tender from the very beginning: corresponding with the supplier, providing support throughout the process, and attending site visits in Malta and Gozo. He also contributed to the clarifications submitted by Medina. Some responses, however, were outside the scope and not fully satisfactory—particularly the reference to "thirty-three thousand sessions per year." Since there are different types of sessions, items, and consumables required, Medina requested statistical information, such as the number of hours per session, number of bags required, and session duration, as these vary depending on the patient. Some sessions cost more due to consumables like bag and needle sizes. The answer provided was, in effect, a "one size fits all."

Dr Ana Thomas remarked whether the Ministry was in a position to answer regarding the sessions, given the wide variety.

Ing. Micallef clarified that he was not requesting detailed data, but rather a statistical margin from Mater Dei's records. He explained that such information could make a significant difference in the long run for the Tender, noting: "A one-

euro difference means thirty-three thousand euros in a year." Medina needed to calculate its expenses accurately so as not to under- or over-estimate.

The Tender also required a demonstration of the machines. Medina enquired who would be responsible for the particular patient undergoing dialysis on a demo machine, and how comparisons could be made if one patient was young and another elderly. It was difficult to assess demo machines equally when test subjects were different.

In response to a question from the Chairperson, Ing. Micallef stated that the answer lay in Clarification 14, but no one present had a copy.

*He then quoted **Question 22**: "We kindly seek confirmation from the Contracting Authority/Department of Contracts that any samples requested as part of selection and award requirements will be used strictly for demonstration and evaluation purposes, and not in any manner applied or administered to patients. We would appreciate written assurances that the samples will be handled solely for non-clinical assessment, in line with applicable safety and regulatory standards."*

*The **answer** referred to Clause 2.34.1, stating: "The sample may be used on patients. The Contracting Authority is unable to be clearer than what this clause stipulates."*

Another concern related to output requirements for low volume, where every machine initially had to include the option for paediatric dialysis. A clarification later stated that not all machines required this option, but that "any other solution to provide paediatric haemodialysis, or low volume, or for patients under thirty kilos may be provided." However, the clarification was vague as to what type of dialysis was required.

*Dr Paris provided the witness with **Clarification Note 5, Question and Answer 1**, referring to Clause 2.22.1.1, and quoted both question and answer:*

Question:

"Reference is made to spec 2.22.1.1 wherein bloodlines for neonates are mentioned. This seems to imply that the HD machines requested need to cater for neonates, in which case competition will be severely restricted as only one known manufacturer can comply with this requirement. Furthermore, the application of haemodialysis in neonates is exceptionally uncommon. Thus, it is highly unreasonable to include a specification that restricts fair competition when alternative solutions are available to address such rare instances of neonates requiring haemodialysis. With the above in mind, please clarify the mention of neonates in the above-mentioned clause."

Answer:

"The Technical Specifications do not state what is being claimed through this clarification. By making reference to Clause 2.33.1, this clause states that 'In the event of the need to dialyse patients whose weight is under 30kg, Tenderers shall be required to provide a dialysis treatment solution for such patients.' Any solution that might treat such patients will suffice and this treatment may not necessarily have to come from machines being provided through this Tender. The expected numbers as stipulated in this clarification will be very low indeed."

Ing. Micallef expressed concern at the phrase "any solution will suffice" since it was too open-ended. There are five types of dialysis procedure, and such wording could even exclude the use of a machine altogether.

Another clarification concerned pressure. The Tender required ***minus 500****, while Medina asked if* ***minus 400*** *would be sufficient, since their superior machine model went down to minus 400. The manufacturer confirmed that blood is damaged at such low pressures. Medina's machines, however, could deliver equal or greater performance with smaller bags due to advanced technology.*

Cross-examination by Dr Farrugia Zrinzo:

Ing. Micallef insisted that if machines had to be demonstrated on patients, it was essential that the selected patients be clinically assessed to be of similar size and weight. It could not be a biased test, where an eighty-year-old patient was used on one machine and a twenty-five-year-old on another.

The Chairperson acknowledged his concern but asked if there was something specific to pinpoint.

Ing. Micallef responded that suppliers needed to know what kind of patients would be used for the demo sessions, and who would bear responsibility.

Dr Farrugia Zrinzo requested the clarification specifying responsibility, but its whereabouts had to be checked.

Witness:

Mr John Soler (ID No. 310480M), *summoned by Dr Paris.*

Mr Soler is the Managing Director of Medina Healthcare.

He explained that in their clarifications, Medina needed to know whether the requirement was for ***sixty-six machines only****, or for sixty-six machines* ***plus other solutions for paediatrics****. The Contracting Authority should specify for every bidder how many machines are required at each location.*

He also noted that the Contracting Authority was requesting prices for consumables, fixed for ten years. He stressed that the parameters for every bidder should be equal. Another issue was responsibility in the event of a recall in the system.

The Tender, valued at twenty-eight million, covers about three hundred patients. Medina submitted around twelve clarifications that were left unanswered or inadequately addressed. One important clarification was about the commencement date of the Tender—whether it began at signing, or only after the six-month period required to install all machines.

With reference to SVPR, he pointed out that the renal unit had not yet been built. He asked what would happen if it was not constructed within the time frame of the Tender. These were, in his view, valid clarifications that concerned all bidders.

Witness:

Ing. Attard Montalto, recalled by Dr Farrugia Zrinzo.

Ing. Attard Montalto clarified that there might only be one or two neonatal dialysis cases in ten years, and in such rare cases, the contractors would be asked to assist.

Regarding time frames, he referred to ***Clarification No. 7****, which asked:*

"Which is the correct time frame between spec number 1.3 and spec number 2.5 because they are in conflict?"

The answer given was:

"There is no discrepancy between 1.3 and 2.5. Both state that the contract is for a period of ten years. 1.3 is referring to the time frame that the machines should be kept running, which is ten years from the date of installation of the machines." He further explained: one might sign the contract, but delivery and installation could take six months. Clause 2.5 states:

"The duration of the Pay per Use Agreement shall run for a period of ten years from the last date of the last signature on the contract."

The Chairperson, Dr Thomas, clarified that upon signing the contract, consumables would be ordered, but the ten-year period would start once the sixty-six machines were delivered and installed.

Final Submissions

Final Submissions by Dr Matthew Paris (Appellant):

Dr Paris explained that the law distinguishes between Regulation 262 and Regulation 270. Under Regulation 270, when objecting at the stage of award or rejection, one must object clearly. Under Regulation 262, when appealing, Article 38 of the PPR requires documents to be clear.

He stressed that Medina firmly believed the Tender should have been ***split into lots*** *to allow for broader competition. He disagreed with the Ministry's claim that this would be an administrative burden, stating that the state has an obligation to promote competition, even if inconvenient. Instead, the Ministry opted for convenience by awarding a single contract for Malta and Gozo.*

He argued that there was no substantiated medical reason for refusing lots, and this also affected pricing. Referring to ***Case 1731 (27 May 2022, Krypton)****, he quoted the PCRB decision:*

"Therefore this board agrees with the argumentation of the appellant that in this specific case, the tendering question could have easily been issued in separate lots. One to cater for the most used adult range i.e. items 6–9 and 12–20, and two other lots for paediatrics (items 1–5) and bariatrics (items 10–11), related to products respectively."

The PCRB had decided in favour of competition in medical devices. Having MDR certification does not eliminate the risk of recalls, and in the event of one, patients would need to be treated abroad. Splitting lots would provide a fallback if a supplier defaulted.

Dr Paris argued that convenience for the Ministry should not outweigh the inconvenience to vulnerable patients requiring haemodialysis.

On time frames, he highlighted contradictions:

Clause 1.3 states:

"The duration of the Pay per Use Agreement shall run for a period of ten years from the last date the Haemodialysis Machines are delivered to the Hospitals and placed into operational use."

Clause 2.5, however, states:

"The duration of the Pay per Use Agreement shall run for a period of ten years from the last date of the last signature on the contract."

He asked for alignment between these provisions.

*He also cited inconsistencies in the **economic and financial standing requirement**:*

"The economic operator should provide its average yearly turnover for the number of years specified in the relevant procurement documents as follows: The minimum average yearly turnover during the past three years (being 2021/2023). The list of principal deliveries is to include similar equipment mentioned above, supplied during the last three years (being 2022/2024)."

The years quoted do not match, and Medina requested clarity.

*On the clinical side, he noted that it took numerous clarifications, an appeal, a hearing, and witnesses to establish that there may be only two neonatal cases in ten years. The Tender should therefore request **sixty-six machines plus a solution for neonates**. The more complex a tender is, the more detailed its specifications should be. Medina was not asking for restrictions but for clearer lists.*

Dr Paris concluded that although he had initially thought clarifications could resolve the issues, the Tender contained so many shortcomings that the best solution would be cancellation and re-issue with all relevant points addressed.

Final Submissions by Dr Alexia J Farrugia Zrinzo (Contracting Authority):

*Dr Farrugia Zrinzo argued that **Case 1731** was not comparable. In that case, the products had different specifications, while in this Tender all machines requested were similar with the same specifications. Therefore, splitting lots was unnecessary.*

She maintained that all clarifications had been answered. Ing. Attard Montalto had clearly explained the time allowed for installation and the ten-year duration with consumables.

She opposed cancellation, stating that the Tender documents were clear, and products were urgently required for vulnerable patients. Any cancellation would unnecessarily extend timelines.

*When asked by Dr Thomas about the position of the Contracting Authority regarding the "sixty-six plus solution" point, Dr Farrugia Zrinzo confirmed: the request was for **sixty-six machines** plus **assistance by the Preferred Bidder in case of a neonate**. She acknowledged that clinically such assistance might be required.*

Dr Paris intervened, stressing that technical forms still required adjustment.

Conclusion of the Hearing

With no further submissions, Dr Ana Thomas thanked all parties and formally concluded the session."

The written pleadings as filed by Medina HealthCare Limited on the 27th June, 2025, together with proof of payment of a deposit in the amount of €50,000.00, wherein it held as follows:

*"**REASONED APPLICATION***

Whereas, the Department of Contracts [hereinafter DOC] issued a call for "Tender is for the Leasing of Sixty-Six (66) Operational Brand-New Haemodialysis Machines with Reduced Environmental Impact on a Pay Per Use Basis s to Mater Dei Hospital, St Vincent De Paul & Gozo General Hospital" (hereinafter 'the Tender);

Whereas Messrs. Medina HealthCare Limited (hereinafter Appellant company) sought to clarify a number of matters and address them through the submission of clarification requests, some of which remained unanswered as at the date of submission of this objection, some others were answered however the reply was either ambiguous and/or unsatisfactory;

*Whereas Messrs. Medina HealthCare Limited (hereinafter Appellant company) feels aggrieved by the contents, or part thereof of the tender, and thereby is submitting its objection in accordance with regulation 262 of the Public Procurement Regulations (PPR) within the time-frame and accompanied with the relative payment (hereby enclosed as **DOC1**) based on the following grievances:*

1. Tender should be divided into lots

1.1 The reasons presented within the tender document, not to divide the tender into lots, is in the opinion of the appellant company, not justified nor proportionate. The Tender stipulates that:

*"This tender **is not divided** into lots, and tenders must be for the whole of quantities indicated. Tenders will not be accepted for incomplete quantities. Tender is not divided in lots since **Items in this tender are interlinked** and the contracting authority requires the **involvement of one contractor rather than multiple contractors** to ensure that treatment, cooperation, operation of machines and training requirements are cohesive."*

1.2 The above was one again reaffirmed by the Department of Contracts through clarification note 12, issued on the 23rd June 2025.

1.3 It is the submission of the appellant company that the above reasons do not constitute a valid justification which merits that competition is artificially narrowed down and this for the following reasons:

***FIRST** Whilst the appellant is at liberty for its choice of procurement procedure and its constitution, the supply of the required machines sourced from multiplier suppliers, subject to them being in full compliance with the tender specifications, should not be of any concern whatsoever to the contracting authority.*

SECOND *In addition, proper planning, and appropriate project management should be enough to address any concerns whatseover of having mulitplier suppliers as opposed to one (1) supplier.*

THIRD *Finally, each and every contractor, once a lot is awarded, is bound by strict contractual obligations which stipulate the rights and duties of the respective parties. If these rights and duties are clearly and appropriately delineated and apportioned, all the minor concerns raised by the contracting authority will be rendered redundant.*

1.4 *Promoting effective competition is also at the core objective of public procurement. The principle of proportionality, as established in public procurement law and recognized in various judgments of the European Court of Justice (ECJ), requires that any measures adopted by a contracting authority must be appropriate, necessary, and proportionate to achieving their legitimate aims. For instance, in cases such as* ***Evropaïki Dynamiki v European Commission***[1]*, the ECJ emphasized that contracting authorities must balance their objectives against the overarching requirement to ensure fair competition and equal treatment.*

1.5 *A lack of genuine or adequate competition undermines these objectives whilst also disadvantaging the contracting authority. If there is no or limited competition, it is the contracting authority which suffers with the risk of obtaining higher offers, bad quality supplies/services or possibly no offers at all.*

1.6 *Reference is being made to the case of the European Court of Justice* ***: C-94/12, Swm Costruzioni 2 SpA and Mannocchi Luigino DI v Provincia di Fermo***[2] *whereby the court highlighted the issue of restrictive procurement practices, ruling that a contracting authority must not design procurement procedures that restricts competition.*

1.7 *The importance of lot division in fostering competition is also highlighted in recitals 76 and 78 of Directive 2014/24, being considered as an essential tool in foster the participation of SMEs in public procurement*[3]*.*

1.8 *This Honourable Board has previously decided upon the importance of dividing tenders into separate lots, inter alia in* ***case 1721*** *of* ***2022****, whereby the Board ordered the cancellation of the tender and the re-issuing of the tender in separate lots*[4] *and highlighting the importance of Regulations 39(3) and 53(6) of Subsidiary Legislation 601.03.*

1.9 *The appellant company further submits that the tender is also in breach of the anti-competition provisions of the Treaty of the Functioning of the European Union [TFEU], specifically articles 101 and 102. The treaty establishes the necessity for competitive neutrality and the prevention of anti-competitive practices in public procurement. Contracting authorities must ensure that procurement procedures are transparent, non-discriminatory, and open to all qualified bidders.*

1.10 *It is as such the submission of the appellant that tender de quo can be easily separated in lots based on location, as follows:*

---

[1] C-629/11 P

[2] 10 October 2013

[3] Recitals 2014/24

[4] Case 1731 –SPD3/2022/010 – Supplies - Framework Agreement for the Provision of Incontinence Diapers Pull-Ups, Pads and Inco sheet for Senior Citizens and Persons with Special Needs for the Ministry for Gozo- Decided 27th May 2022

Lot 1 Mater Dei Hospital
Lot 2 St Vincent De Paul
Lot 3 Gozo General Hospital

1.11 In addition and without prejudice to the aforesaid, in view of the critical nature of the supplies being procured [life-saving treatment for kidney failure], it is respectfully submitted that the Contracting Authority should give due consideration to the possibility of awarding the tender to multiple suppliers. This recommendation is not only aimed at enhancing competition and market accessibility, but also reflects a prudent and responsible approach to ensure continuity of supply.

1.12 Securing at least two [2] distinct sources would provide an essential layer of contingency, thereby safeguarding against any disruption in delivery or performance by a single supplier. Ultimately, such a measure would be in the best interest of patient care, ensuring uninterrupted access to essential products and services. In view of the above, an alternative split could be as follows:

Lot 1 Thirty-three (33) Operational Brand-New Haemodialysis Machines with Reduced Environmental Impact
Lot 2 Thirty-three (33) Operational Brand-New Haemodialysis Machines with Reduced Environmental Impact

1.13 Alternatively, the Contracting Authority may consider dividing the tender into separate lots based on patient categories, namely one for paediatric patients and another for adult patients. Such a division would not only enhance clarity in terms of technical specifications and evaluation criteria but would also promote broader competition and ensure that the specific needs of each patient group are adequately addressed by specialized suppliers. In view of the above, an alternative split could be as follows:

Lot 1 Supply for paediatric patients
Lot 2 Supply for adult patients

2. Tender drafting is ambiguous and not clear

2.1 It is the submission of the appellant company that, the Contracting Authority has a fundamental obligation to ensure that the tender document is clearly and comprehensively drafted, allowing all interested economic operators to participate on an equal and informed basis. This obligation includes the duty to address any ambiguities or uncertainties brought to its attention during the clarification period. The failure to provide a clear and unambiguous tender document from the outset, coupled with the failure to adequately clarify such ambiguities when raised through official channels, constitutes a clear and material breach of the applicable public procurement regulations, undermining the principles of transparency, equal treatment, and legal certainty.

2.2 In joined cases C-72/10 and C-77/10, judgment of February 16th, 2012[5] it was held that a tender " … must be drawn up in a clear, precise and unequivocal manner, to make it possible for all reasonably informed tenderers exercising ordinary care to understand their exact significance and interpret them in the same way, and to circumscribe the contracting authority's

[5] Costa and Cifone

discretion and enable it to ascertain effectively whether the tenders submitted satisfy the criteria applying to the relevant procedure".

2.3 The appellant company submits that, the tender document, as drafted, is in breach of article 38 of the PPR, and notwithstanding multiple clarifications, the tender document fails the ambiguity test, as follows:-

2.3.1 Clarification Note 5 [Question/Answer 1] fundamentally altered the tender specifications

The clarification issued on 16th May 2025, stating that "any solution that may treat such patients will suffice and this treatment may not necessarily have to come from the machines being provided through this tender," effectively introduces a material alteration to the original tender requirements. However, rather than providing clarity, this statement creates an open-ended interpretation of the scope, without establishing clear technical specifications or objective criteria upon which bids will be evaluated. This lack of precision undermines the principles of transparency and equal treatment, and renders the evaluation process arbitrary and legally questionable under the applicable public procurement framework.

This clarification is clearly in breach of the tender document, which has been specifically designed to and has as its scope the, "The supply on a Pay per Use basis, of a total of Qty Sixty-Six (66) fully operational brand-new Haemodialysis Machines."

2.3.2 Conflicting time-frames

The tender document as drafted includes conflicting duration time-frames, since in provision 1.3 [Section 3 – page 20] the tender document stipulates that the duration of the tender is for a period of "ten years from the last date the heamodialysis machines are delivered", provision 2.5 [Section 3 – page 21] stipulates that the duration shall, "run for a period of ten years from the last date of the last signature on the contract"

This has been outlined throughout the clarification period, however the contracting authority has failed to address this anomaly, and persisted in its endeavours.

Hereunder are extracts from the tender document, which confirms the conflicting time-frames mentioned above:

1.3	The duration of the Pay per Use Agreement shall run for a period of ten (10) years from the last date the Haemodialysis Machines are delivered to the hospitals and placed into operational use.

2.5	The duration of the Pay per Use Agreement shall run for a period of ten (10) years from the last date of the last signature on the contract.	N/A	Mandatory

2.3.3 Incongruence in the years of scope [selection criteria]

It is noted that the tender document provides inconsistent interpretations of the term "last three years" across different selection criteria. Specifically, for the purposes of assessing economic and financial standing, the reference years are stated as 2021, 2022, and 2023, whereas for technical and professional ability, the reference period is listed as 2022, 2023, and 2024. This discrepancy

creates ambiguity and legal uncertainty, and the Contracting Authority is under a clear obligation to address and rectify this anomaly to ensure consistency, transparency, and fairness in the evaluation process in accordance with the principles of public procurement.

Economic and Financial Standing (Note 2)

Average yearly turnover

The economic operator should provide its average yearly turnover for the number of years specified in the relevant procurement documents as follows:

The minimum average yearly turnover during the past 3 years (being 2021-2023) shall be not less than €1,500,000 per year. This information shall be included in the indicated field of the integrated ESPD.

Technical and Professional Ability (Note 2)

List of Principal Deliveries of a Similar Nature, being supply of Haemodialysis machines, to be submitted through the Tender Response Format.

The list of principal deliveries is to include similar equipment mentioned above, supplied during the last 3 years (being 2022-2024) and is to substantiate the following:

3. <u>Failure to address technical clarifications</u>

3.1 It is with considerable regret that the economic operator finds itself compelled to file this pre-contractual remedy under Regulation 262 of the Public Procurement Regulations. This course of action has become necessary solely due to the failure of the Contracting Authority to address a number of critical clarifications which were duly submitted within the stipulated timeframe.

3.2 The failure by the Contracting Authority to provide timely, clear, and comprehensive responses to legitimate requests for clarification is not merely an administrative shortcoming. It represents a serious procedural deficiency which has obstructed the economic operator's ability to participate in the procurement process on a fully informed and equal basis, as is required by law.

3.3 Worse still, this failure demonstrates an outright disregard for the basic principles of transparency, equal treatment, and legal certainty that underpin public procurement procedures. The Contracting Authority's inaction has effectively undermined the integrity of the tendering process and eroded the trust that economic operators are expected to place in the procurement system.

3.4 Such conduct is particularly troubling when viewed against the expected standards of public sector corporate governance. A Contracting Authority entrusted with the disbursement of

public funds has a duty not only to comply with legal requirements, but to uphold the highest levels of administrative diligence, accountability, and responsiveness. In this instance, those obligations have clearly not been met.

3.5 In view of the above, the filing of the pre-contractual remedy is not just justified, but necessitated by the systemic failure of the Contracting Authority to respect its procedural duties and to safeguard the fair and lawful conduct of the procurement process.

NOW THEREFORE, whilst reserving the right to put forward further submissions, the Appellant company hereby requests:

i. To cancel, modify, remove set aside and/or in any other manner give any other direction in accordance with article 262 of the Public Procurement regulations;

ii. In accordance with article 90[4] of the PPR, take such interim decisions as required, including but not limited to order the defendants to provide the necessary clarifications as requested by the appellant company;

iii. To do anything which is ancillary and conducive to the proper execution of this decision;

iv. To refund the deposit paid;

Appellant company is hereby reserving the right to present further evidence, both orally or in written, during the hearing*."*

The written reply as filed by the Central Procurement and Supplies Unit on the 2nd July, 2025, with a stamp bearing the date of the 3rd July, 2025 (hereinafter the 'Contracting Authority') wherein it held as follows:

"Reply of the Department of Contracts (DOC) and the ***Central Procurement and Supplies Unit*** *(CPSU) on behalf of the Department of Health to the reasoned application lodged by Medina Healthcare Limited (the applicant) in terms of regulation 262 of the Public Procurement regulations (PPR) in relation to a number of a number of technical specifications.*

On the 17th of April 2025 a call for ***for the Leasing of Sixty-Six (66) Operational Brand-New Hemodialysis Machines with Reduced Environmental Impact on a Pay Per Use Basis s to Mater Dei Hospital, St Vincent De Paul & Gozo General Hospital*** *was issued*

During the clarification period economic operators submitted a number of requests for clarification, to which the contracting authority replied.

The applicant felt aggrieved and filed this application, alleging breach of regulation 262.

DOC and CPSU humbly disagrees with the appeal and are filing a preliminary plea and the below submissions in reply, in the same order of the issues raised by the applicant.

Submissions:

Preliminary Plea

1. *The applicant failed to indicate which ground/s of regulations 262 of the PPR on which it is basing this action;*

2. *Regulation 262(1) provides an exhaustive list of remedies and instances where this particular action can be resorted to, however the applicant failed to identify the ground on which it is basing its action, leading to an ambiguous appeal which thus should be rejected;*

On First Grievance – Tender should be divided into lots

3. *The applicant argues that the tender should have been divided into lots and gives a number of alternative lots, namely a lot of each institution, 2 lots for half the quantities each or 2 lots; one for paediatric patients and one for adult patients;*

4. *The DOC and CPSU respectfully disagrees with the grievance since CPSU is seeking to procure 66 machines of the same type;*

5. *CPSU as a contracting authority constantly procures items for all the health entities within the Ministry for Health and Active Ageing and does not issue separate lots for different hospitals or clinics, but procures for the national health service as whole;*

6. *In this case CPSU is seeking to procure the lease of 66 machines for the various health entities and since the product is one and the same it was not divided into lots;*

7. *There are various practical reasons why this decision was taken, firstly the procurement of a larger quantity certainly puts CPSU as a contracting authority in a better bargaining position to get a better price due to larger quantities;*

8. *Moreover the contracting authority is procuring for all major hospitals within the Ministry for Health and dividing the tender into lots would also mean that training has to be provided on 3 different machines;*

9. *This would create difficult when it comes to the movement of workers who might be trained on a machine and might need to work in a different hospital within the national health system;*

10. *It must be pointed out that this tender is for a period of 10 years and thus the movement of workers is very likely;*

11. *Moreover not dividing the tender into lots does not limit any form of competition since this refers to the same product and not to various products (in which case an economic operator might not be able to provide all products;*

12. *If an economic operator is able to bid for one lot, it will be in a position to bid for all the lots;*

13. *For these reasons this first grievance should be rejected*

On the Second Grievance: Tender Drafting is ambiguous and not clear

14. *DOC and CPSU rebut to this grievance since tender drafting is clear and the clarifications have just made the tender clearer;*

15. *Regarding the alleged ambiguity created by clarification note 5, this note actually cleared any ambiguity that there might have been as will be further explained by the witnesses during the sitting;*

16. *The applicants respectfully, have cited very selective parts of the question and the answer to such clarification and thus CPSU submits that such question and answer must be interpreted in a wider sense and within the scope of the whole tender;*

17. *With regards to the conflicting time frames, CPSU also respectfully submits that there is no conflicting provision, and in any such case, if there was a conflicting provision, this has been clarified by means of clarification note 12*

Question 2:

Please advise which is the correct timeline between Spec No 1.3 & Spec Number 2.5 because they are in conflict.

Answer 2:

There is no discrepancy between Clauses 1.3 and 2.5. Both state that the contract is to run for a period of 10 years. Clause 1.3 is referring to the time period that the machines are to be kept running (which is 10 years from the date of installation of the machines), whilst Clause 2.5 is referring to the time limit of the consumables, which allows the contracting authority to continue ordering the required consumables up to 10 years from signing of the contract.

18. *With regards to the applicable years for financial standing, the applicants should have sought a clarification during the clarification period, however, without prejudice to this, the tender was clear in stating that the applicable years were the past 3 years;*

19. *Without Prejudice to the above submissions, should this Honourable Board decide to uphold this grievance in whole or in part, the alleged ambiguities mentioned can be clarified through a clarification note and the cancellation of the tender is not necessary;*

On this Third Grievance – Failure to address technical clarifications

20. *DOC and CPSU submit that the applicant should have indicated which clarification requests were not addressed in the reasoned application;*

21. *Secondly CPSU and DOC submit that to their knowledge, all clarification requests have been addressed substantively*

22. *DOC and CPSU submit that they acted through this procurement process in the utmost good faith and diligence and thus strongly rebuts the claim that it has disregarded the basic principles of transparency, equal treatment and legal certainty;*

For the above reasons and submissions which will be further explained and evidenced during the

sitting, DOC and CPSU humbly request that the application ought to be rejected and the tender document confirmed as published.

DOC and CPSU reserve the right to make additional submissions, orally or in writing and to present evidence to sustain their position.

With Respect."

The opening and closing submissions of the Appellant and the Contracting Authority as delivered by their legal representatives;

Considers;

This Board notes that the Appellant has brought forward several grievances with respect to the Tender Document in the appeal filed in terms of Regulation 262 of the Public Procurement Regulations (hereinafter the 'PPR'). The Appellant's first contention is that the tender in question should have been divided into lots, the second revolves mainly with the alleged ambiguity in the Tender Document's drafting making it unclear, and further that the Contracting Authority failed to reply to critical clarifications in time. The Contracting Authority on the other hand, whilst refuting all grievances brought forward by the Appellant raised a preliminary plea regarding the Appellant's alleged failure to "*indicate which ground/s of regulations 262 of the PPR on which it is basing this action".*

A. Preliminary Plea

In its submissions on the preliminary plea, the Appellant drew a comparison between what is required in terms of an appeal filed under Regulation 262 of the PPR as opposed to an appeal filed under Regulation 270 of the PPR, which respectively hold as follows:

> *"262. (1) Prospective candidates and tenderers may, within the first two-thirds of the time period allocated in the call for competition for the submission of offers,* ***file a reasoned application*** *before the Public Contracts Review Board:"* (This Board's added emphasis).
>
> *"270. Where the estaimated value of the public contract meets or exceeds five thousand euro (€5,000) any tenderer or candidate concerned, or any person, having or having had an interest or who has been harmed or risks being harmed by an alleged infringement or by any decision taken including a proposed award in obtaining a contract, a rejection of a tender or a cancellation of a call for tender after the lapse of the publication period,* ***may file an appeal by means of an objection*** *before the Public Contracts Review Board,* ***which shall contain in a very clear manner the reasons for their complaints."*** (This Board's added emphasis).

This Board notes that whilst there admittedly exists a difference in wording, this does not mean that any appeal filed under Regulation 262 of the PPR should be any less detailed in terms of grievances set forth and supplementary submissions. Therefore, this Board does not fully agree with the submissions of the Appellant in this sense. However, from the acts of this appeal, it does not emerge that the Appellant's written appeal fell foul of the requirements of Regulation 262, on the contrary, the Appellant's grievances are clear, substantiated and well explained – so much so that the Contracting Authority found no difficulty in replying to each and every one of the grievances as set forth.

Therefore, the Contracting Authority's preliminary plea is being rejected as unfounded and this Board shall continue considering the Appellant's appeal on the grievances proper.

B. Tender Should Be Divided Into Lots

In the Appellant's first grievance, the Appellant sets forth several arguments in favour of splitting the tender into lots. Reference was also made to the judgment delivered by the PCRB on the 27th May, 2022 Case No. 1731. The Contracting Authority on the other hand argues that in this present case the tender is requesting one and the same product across the board, and not different products, amongst other arguments. The witness summoned by the Appellant Dr Attard Montalto explained that standardisation would ensure smoother operations as well as this would ensure that all patients were receiving the same treatments, whether they receive it at Saint Vincent de Paul, Mater Dei Hospital or Gozo General Hospital.

This Board has taken cognisance of and reviewed the decision quoted by the Appellant delivered by the PCRB, and whilst it is true that the PCRB in that case highlighted the importance of safeguarding competition and equal access to the tendering procedure to economic operators, it is of note that in that case the products in question were not one and the same. This Board shall quote verbatim from the decision:

> *"c) Reference is finally made to the Tender Dossier Section 3 Specifications / Terms of Reference, page 18, paragraph 4. Therein a table listing 20 items to be fulfilled and supplied by the eventual economic operator awarded the tender procedure. Items 1 to 5 mainly refer to 'Paediatric' related products which amount approximately to 5% of the whole population of quantities. Items 10 and 11 mainly refer to 'Bariatric' related products which amount approximately to only 1% of the whole population of quantities. The Board opines that enough proof has been presented by the Appellant to ascertain that such Paediatric and Bariatric products can only be provided by one or very few suppliers, thus artificially narrowing competition. On the other hand, items 6 to 9 and 12 to 20, which represent approximately 94% of the population can be furnished by a much larger pool of suppliers.*
>
> *d) Therefore, this Board agrees with the argumentation of the Appellant that in this specific case, the tender in question could have easily been issued in separate lots, one (1) to cater for the most used 'Adult' range, i.e. items 6 to 9 and 12 to 20, and two other lots for 'Paediatric' (items 1 to 5) and 'Bariatric' (items 10 and 11) related products respectively."*[6]

In the above-quoted case therefore, the PCRB was correct in its evaluation and decision, wherein it made far more sense in the circumstances to split the call into lots per product, however, the same cannot be said in this case. No good reason was brought before this Board as to why the call in question should be split into lots, particularly since it is the same product in large quantities, spread over three hospitals which decision was taken for the reasons as provided by the Contracting Authority.

Therefore, the Appellant's first grievance is being rejected.

C. Tender Drafting is Ambiguous and Unclear

---

[6] Page 6 of the decision of the Public Contracts Review Board – "Case 1731 –SPD3/2022/010 – Supplies - Framework Agreement for the Provision of Incontinence Diapers Pull-Ups, Pads and Inco sheet for Senior Citizens and Persons with Special Needs for the Ministry for Gozo" dated 27th May, 2022.

The Appellant's grievance on the ambiguous and unclear drafting of the Tender Document may be split into several different points, namely:

i) Clarification Note 5 fundamentally altered the tender specifications;
ii) Conflicting Time-Frames;
iii) Incongruence in the years of scope.

Clarification Note 5 fundamentally altered the tender specifications;

On this point in particular the Appellant laments that the answer to the question put forward in Clarification Note 5 on the solution required for neonates altered the tender specifications. From the testimony on this point as well as oral submissions by the Contracting Authority, it remained unclear even to this Board whether the Contracting Authority would require:

a) the economic operator to provide for a solution in its bid i.e. a product which caters for neonates, and if so, which solution and which specifications are acceptable; OR
b) mere assistance to arrive at a solution for neonates by the economic operator, whatever that may mean; OR
c) none of the above (and this is being stated in view of the parting question made by Ing. Attard Montalto directly to this Board after this Board drew the hearing to a close, whereby he asked whether the Contracting Authority could at that juncture exclude neonates altogether).

Whilst the Contracting Authority is undoubtedly acting with the patient's best interests at heart, it must also take full responsibility of its obligation to provide a clear, unambiguous Tender Document – which should not be drafted in such as way that it may be interpreted differently by economic operators. With respect, this Board deems that in this particular instance, the Tender Document is ambiguous and the answers to the clarification request in this sense were not clear enough to set aside any doubt which may have been created. The Appellant's legal counsel Dr Paris was correct to submit that it took a clarification request, an appeal, a hearing and a witness to testify to arrive at the conclusion that one or two neonate cases may result throughout the term of the contract, but it remains a query as to what is truly required of the economic operators.

This Board therefore, in view of the foregoing and in the circumstances of this case, hereby directs the Contracting Authority to immediately and without further delay clarify in writing to all economic operators as follows: <u>whether a neonate solution is in fact required, and if the answer is in the affirmative, then the Contracting Authority must clearly and unequivocally underline which solutions shall be deemed acceptable.</u>

Conflicting Time-Frames;

Hereagain, this Board agrees with the Appellant's qualms as to the duration of the Pay per Use Agreement. Notwithstanding the explanation provided by Ing. Attard Montalto in his testimony, it clearly emerges from the Tender Document that the period of ten (10) years is listed as commencing at different junctures in Clause 1.3. and Clause 2.5. of the Tender Document. It would be far more beneficial for all parties concerned for the Contracting Authority to clarify this inconsistency in such a way so as to have the two Clauses streamlined, <u>and the Board hereby orders the Contracting Authority to do so without further delay.</u>

Incongruence in the years of scope.

On this point, the Appellant refers to excerpts of the Tender Document where on the one hand "the past 3 years" are defined as being years 2021-2023, and on the other hand "the last 3 years" are then defined as being years 2022-2024. The Contracting Authority states that the Tender Document was clear and that even if this Board deems it to be ambiguous, then this may be clarified through a clarification note and that the cancellation of the tender is not necessary.

This Board, having reviewed the excerpts complained of, determines that the Appellant is justified in complaining of the fact that the Tender Document refers to the last/past three years at two different junctures in the Tender Document, which years are then strangely defined differently, one refers to the last three years as being 2021, 2022 and 2023, whereas at the other juncture the years are referred to as being 2022, 2023 and 2024. This state of affairs is not only easily avoidable, but naturally causes confusion, and the Contracting Authority ought to clarify this requirement once and for all by issuing the appropriate clarification as to which precise years are required, rather than referring to them as the last or past number of years. This Board hereby orders the Contracting Authority to issue a clarification in this respect in the immediate, clearly stipulating which years the Tender Document is referring to e.g. calendar year 2022, 2023 et cetera.

As an aside, this Board cannot but make an observation as to the significant number of clarification requests put forward by various economic operators, which is, in and of itself indicative as to the large number of questions raised by the way the Tender Document was drafted. Whilst this Board does not believe that in the present circumstances a cancellation is warranted, this ought to be looked into to avoid unnecessary waste of resources for all those involved in the tendering process, particularly in all efforts spent in replying to clarification requests.

Therefore, the Appellant's grievance is being limitedly upheld in line with the above considerations and this Board shall be ordering the Contracting Authority to make the necessary clarifications in the immediate as per the orders given further down in this judgment.

D. Failure to Address Technical Clarification Requests

This Board shall be delving into the Appellant's grievance that the Contracting Authority failed to address technical clarification requests, and that the Contracting Authority's replies to some clarification requests were in and of themselves unsatisfactory. The Contracting Authority on the other hand holds that to its knowledge, all clarification requests were answered, and that the Contracting Authority acted in utmost good faith and diligence.

During the hearing of this appeal, the witness as produced by the Appellant Mr Soler also made reference to unanswered clarification requests. This Board, during the hearing of this appeal, directed the Appellant to divulge which clarification requests went unanswered. The Board was informed *seduta stante* that the Appellant would be filing a note in this sense within the day if the clarification requests which were allegedly unanswered are traced, failing which it is to be presumed that they have not been so traced. This Board has yet to receive said information, therefore, in the absence of evidence to substantiate the said allegation as set forth by the Appellant, this Board hereby rejects this grievance as set forth by the Appellant.

It is of note, that the Contracting Authority answered tens of clarifications regarding the Tender Document and there is nothing that emerges from the acts of the same tendering process that casts any shred of doubt on the Contracting Authority's adherence to the basic principles of transparency

and equal treatment. Therefore, this Board determines further that submissions to the contrary are unfounded.

DECIDE

The Board, in view of the foregoing and on the basis of the considerations as outlined above, declares and decides to limitedly uphold the appeal filed by Medina HealthCare Limited, and orders the Contracting Authority to:

a) Immediately clarify whether a neonate solution is in fact required, and if the answer is in the affirmative, then the Contracting Authority must clearly and unequivocally underline which solutions shall be deemed acceptable;

b) Immediately clarify at which juncture the time period of ten (10) years is set to commence;

c) Immediately clarify and stipulate which set of years the Tender Document by referring specficially to the calendar years;

This Board further orders that once the Contracting Authority fulfils the orders as stipulated above in full, it extends the deadline for submission for tenders by 40 days.

In view of the circumstances, the Board further decides to re-imburse the deposit paid by the Appellant Medina HealthCare Limited without delay.

Dr Ana Thomas	**Mr Keith Victor Grech**	**Mr Lawrence Ancilleri**
Chairperson	**Member**	**Member**