

PUBLIC CONTRACTS REVIEW BOARD

Case 2177 - Call for Remedies 593 – CT2246/2025 – Tender for the Supply of Closed Type Neonatal Incubators for the Neonatal and Paediatric Intensive Care Unit at Mater Dei Hospital

27th November 2025

The Board,

Having noted the call for remedies filed by Dr John L. Gauci acting for and on behalf of **Reactilab Limited**, (hereinafter referred to as “*the Appellant*”) filed on the 16th September, 2025;

Having also noted the letter of reply filed by Dr Mark Anthony Debono, Dr Leon Camilleri and Dr Alexia J. Farrugia Zrinzo acting for and on behalf of the **Department of Contracts (D.O.C.)** and the **Central Procurement and Supplies Unit (CPSU)** (hereinafter referred to as “*the Contracting Authority*”) filed on the 22nd September, 2025;

Having further noted the subsequent application filed by Dr John L. Gauci acting for and behalf the Appellant filed on the 19th of November, 2025 requesting the Board’s leave to concede the brief testimony of the Appellant’s witness;

Having heard and evaluated the testimony of the witness Ing. Chris Attard Montalto as duly summoned by Dr John L. Gauci acting for and behalf of the Appellant and having examined the documents submitted during the proceedings by the witness herein marked as *CAM1*, *CAM2*, *CAM3* and *CAM4*;

Having heard and evaluated the testimony of the witness Mr Salvatore Bramato as duly summoned by Dr John L. Gauci acting for and behalf of the Appellant and having examined the document submitted during the proceedings by Dr John L. Gauci herein marked as *JLG5* and *JLG6*;

Having heard and evaluated the testimony of the witness Ms Angie Haken as duly summoned by Dr John L. Gauci acting for and behalf of the Appellant;

Having noted and evaluated the minutes of the Board sitting of the 4th November, 2025 and those of the 24th November, 2025, respectively hereunder reproduced;

Having heard the submission of the Contracting Authority whereby the Contracting Authority requested the Board to concede an adjournment given that their main witness, Consultant Mr Ryan Farrugia, was indisposed of to attend for the hearing held on the 4th of November, 2025 and whereby the Appellant did not find any objection to such request; the Board upheld the request for adjournment and thereby adjourned the appeal hearing for the 24th of November, 2025 at 07:30hrs;

Having heard and evaluated the testimony of the witness Mr Stephen Debono as duly summoned by Dr John L. Gauci acting for and on behalf of the Appellant;

Having heard and evaluated the testimony of the witness Consultant Mr Ryan Farrugia as duly summoned by Dr Leon Camilleri and Dr Alexia J. Farrugia Zrinzo acting for and on behalf of the Contracting Authority;

Having taken cognizance and evaluated all the acts and documentation filed, as well as the submissions made by representatives of the parties;

Minutes

Case 2177 – Call for Remedies 593 – CT2246/2025 – Tender for the Supply of Closed Type Neonatal Incubators for the Neonatal and Paediatric Intensive Care Unit at Mater Dei Hospital.

The tender was issued on the 7th of August 2025, and the closing date was the 6th of October 2025.

The estimated value of the tender, excluding VAT, was €127,119

On the 16th of September 2025, Reactilab Limited, lodged an appeal against the Central Procurement and Supplies Unit (CPSU) – the Contracting Authority, and the Department of Contracts. In accordance with Regulation 262 of the Public Procurement Regulations.

On the 4th of November 2025, the Public Contracts Review Board (PCRB), composed of Dr Vincent Micallef as Chairman, Ing Dr Damien Gatt and Mr. Lawrence Ancilleri, as members, convened a public hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – Reactilab Limited. (C56095).

Dr John L Gauci – Legal representative.

Mr Stefan Debono – Company Representative.

Ms Nour Benmatoug – Company Representative.

Contracting Authority – Central Procurement and Supplies Unit (CPSU).

Dr Alexia Farrugia Zrinzo – Legal Representative.

Dr Leon Camilleri – Company Representative.

Ing. Chris Attard Montalto -- Chief Biomedical Engineer and Spec Drafter.

Ms Branica Amato Gauci – Head of Procurement.

Ms Marika Cutajar – Procurement Manager.

Department of Contracts.

Dr Mark Anthony Debono – Legal Representative.

Recommended Bidder – Not Applicable.

Opening Statements.

Dr. Vincent Micallef, Chairman of the Public Contracts Review Board, welcomed the parties present, namely the Appellant, Reactilab Limited, and the Contracting Authority, the Central Procurement and Supplies Unit (CPSU).

Initial Submissions.

Initial Submissions by Dr. John L. Gauci (for the Appellant).

Dr. Gauci, representing Reactilab Ltd., requested a Precontractual Remedy. Three of the specifications in the tender are either tailor-made for one manufacturer or unduly restrictive.

Specification 2.3.2 requires a rotatable mattress to allow access to the head for airway manoeuvres. GE is the only manufacturer that has this feature. It is prohibited by law to request a tailor-made product, and the witnesses will testify that there is no need for this requirement.

Specification 2.3.5 requires the incubator to have a weighing scale with a range of 300–9000 g. Reactilab is proposing 7000 g, which is still too high for a newborn baby. The average weight of newborns, according to official statistics, is 3000 g, with 0.2% of babies weighing around 4500 g.

Specification 2.4.1 requires a temperature range of 20°C to 39°C. The witnesses will verify that 20°C is not clinically recommended, and Reactilab proposes 23°C.

These three grievances appear to be either tailored or restrictive of competition.

Initial Submissions by Dr. Leon Camilleri (for the Contracting Authority).

Dr. Camilleri explained that it is the CPSU that determines the needs of the tender. The CPSU must procure products that are more flexible and offer more features to provide a better service.

These three particular specifications are more flexible in use, and specification 3.3.2, concerning rotatable mattresses, helps practitioners by reducing the need to handle the babies. The specifications are justified, and while every specification imposes restrictions, these are not unlawful.

Any alleged claim that these requirements were tailor-made for a certain manufacturer must be confirmed by the Appellant, since CPSU is aware that several manufacturers can supply such products.

Witnesses.

Ing. Chris Attard Montalto (ID 260567M) — Summoned by Dr. John Gauci.

Engineer Chris Attard Montalto, Director for Medical Equipment within the Health Ministry, has been working for 34 years. Together with the assistance of doctors and nurses, he drafted the specifications of the tender, mainly the incubators for MPICU. He replied to all clarifications submitted.

Regarding the rotatable mattress (spec. 2.3.2), the less the baby is handled, the better. There are about four companies that have this feature, which allows healthcare providers easier access to the infant's head.

Dr. Gauci referred to Clarification Note 5 about 'Rotable Mattress to allow access to the head for airways manoeuvres', where the note requested that this feature be removed. Dr. Gauci quoted the answer:

'This feature is very often utilised clinically by the doctors and the nurses, as it allows them to rotate the baby without having to handle the patient. This feature is required and is to remain as a mandatory requirement.'

The witness verified that these incubators were currently in use and that staff found them useful. The make of the incubators was ‘Giraffe of GE’; however, the witness presented other manufacturers who have similar products. Referring to Question 1 of Clarification Note 5, he quoted:

‘This specification requires rotatable mattress which is the lock out specification feature pertaining to only one manufacturer GE’.

Dr. Gauci asked why the CPSU did not deny this.

The Chairman argued that since there were other competitors who could tender for that particular mattress, why was the clarification question not answered in that way?

Dr. Gauci mentioned the appeal, where a specific allegation was made that the tiltable mattress was a tailor-made specification for GE, and this was not denied in the CPSU’s answer.

Dr. Camilleri objected to the question.

The Chairman upheld the question and instructed Dr. Gauci to proceed.

Dr. Gauci insisted on knowing why the evidence presented was not included in the reply to their questions.

The Chairman clarified that point 12 was redundant and repeated the question: why was the evidence brought forward, not included in the Appellant’s appeal answer?

The witness replied that there were other companies that had the requested product but failed to provide proof with the letter. When drafting the specifications, they looked for particular features, and the rotatable mattress was considered necessary. This feature originated from Giraffe GE; however, they had found that other companies also offered it. They did not limit the specification to one company.

Ing. Attard Montalto admitted that they did not verify whether other models complied with the technical specifications requested in the tender.

Verbal:

‘Ing. Chris Attard Montalto exhibited a set of four documents:

1. **Infant Incubator CAM1**
2. **Satis + CAM2**
3. **Hill-Rom CAM3**
4. **Giraffe CAM4**

A copy of each was distributed among all parties.’

Dr. Gauci stated that the model currently in use is the Giraffe Incubator Core Station and that there was no dispute about it. Referring to document CAM3 (Hill-Rom), the witness quoted:

‘With controlled thermal support and complete access and visibility, The GE Giraffe Warmer is designed to meet the needs of NICU/PICU patients and clinicians.’

Dr. Gauci showed that Hill-Rom was using a component from GE—the Giraffe Warmer—however, the Hill-Rom Isolette C2000 did not have a rotating mattress. Ing. Attard Montalto referred to and quoted:

‘Its unique baby Susan offers easy access to infants without having to remove them from the mattress. Its intelligent recessed heater design enables advanced bed warming, while

its updated hourglass heat profile optimizes heat coverage to keep the rotating mattress and baby warm with minimal heat loss.’

Dr. Gauci stated that Peak Medical Resources supply GE with a rotating mattress, while Hill-Rom Isolette does not have this feature. The witness argued that, in his view, he was seeing an incubator with a rotating mattress.

Dr. Gauci asked about the difference between a rotating mattress and a tiltable mattress. A tiltable mattress can only be inclined, whereas a rotating mattress can turn 360 degrees. The witness was asked to indicate, from document CAM2 (Satis+), information about the rotating mattress, and he quoted:

‘The sliding mattress rotating as optional extra.’

The witness had seen the brochure but not the manual, and he did not know whether “rotating” meant 360 degrees. Pages from the manual were handed to the witness and to all parties. Dr. Gauci invited the witness to see whether the rotating mattress in the manual complied with the tender specifications as interpreted by the Contracting Authority, since it was marked as rotating 0 to 90 degrees.

The witness insisted that clause 2.3.2 of the Public Specifications requested ‘Rotatable mattress to allow access to the head for airways manoeuvres’, and the angle was never mentioned. The Contracting Authority would therefore have to accept this offer, since it still rotates.

Dr. Micallef verified that the witness had said the rotating mattress had to rotate 360 degrees, and the witness admitted his mistake, acknowledging that this was not specified in the tender.

Ing. Attard Montalto admitted that 0–90 degrees is an improvement over a fixed mattress, though 360 degrees would be preferable. However, the Contracting Authority had omitted this specification in the tender.

Referring to brochure CAM1 (Ningbo Medical Device), the mattress rotates 360°. This manufacturer is based in China. The witness knew the brand but had never used its products.

In the Declaration of Conformity, clause 5, 1.2.3, the Contracting Authority required that medical devices comply with the Medical Devices Directive; such products must be CE-marked to be permitted in Malta. The witness quoted from page 5 of the tender:

‘EU based Importers Status (Medical devices (including active implantable medical devices), in vitro diagnostic medical devices and/or personal protective equipment) A bidder, either on his/her own capacity, or through subcontracting, must meet the requirements of the applicable regulations.’

He knew the representative of Ningbo in Malta and confirmed that they were offering the YP-3100B device, though conformity was not yet verified. At this stage, he did not have the offer in hand, as this was precontractual.

Referring to the weight requirement of 9 kg, the witness stated that the MPICU cares for long-term babies with conditions that cause them to remain in the incubator as they grow, sometimes reaching up to 9 kg. The companies listed in the brochures can meet this requirement.

Dr. Gauci noted that since the Giraffe GE range is ‘300 g to 8 kg’, it does not meet the 9 kg specification. According to the agent from Ningbo, their product satisfies the 9 kg requirement. The Hill-Rom document does not mention weight.

Regarding the temperature, the Appellant argued that a baby is not kept at 20°C. The witness stated that this clinical requirement was requested by doctors. When a patient suffers from meningitis, a cooler environment is needed to lower the body temperature. This provides flexibility for clinicians.

Cross-Examination by Dr. Leon Camilleri.

Ing. Attard Montalto confirmed that he consulted with consultants and nurses in the MPICU, which is the Intensive Care Unit for children. The specification 'Rotable mattress to allow access to the head for airway manoeuvres' aims to reduce the handling of babies by clinicians.

Handling of patients can risk injury to the patients, especially in a highly stressful environment. This feature is indispensable for the nurses. The request was for rotation, without a specified angle. Ing. Attard Montalto was the tender drafter, and the compliance of every product would later be evaluated by the Evaluation Committee.

Referring to the weighing scale, with a range of 300–9000g, a baby could potentially grow to that weight in the case of a long-term disease. The MPICU nurses would have to remove the baby from the incubator if it did not reach the required weight.

Referring to 'Convective heater allowing air temperature settings between 20°C to 39°C', the CPSU for Mater Dei is requesting clinical flexibility in temperatures for the babies.

Re-Examination by Dr. John Gauci.

Ing. Attard Montalto confirmed that he was involved in drafting the tender and conducting market research for this equipment. On page 3, clause 1.3 of the tender document, the tender requested ten incubators for an estimated procurement value of €127,000, based on previous prices.

Mr. Salvatore Bramato (ID CA58275QE) — Summoned by Dr. John Gauci

Mr. Bramato was the General Manager of Atom Medical Corporation, based in Italy, and responsible for European operations, including Malta. He has worked with a medical company since 1999, particularly in neonatal care. He is a technical engineer who has dealt with medical staff for many years. Atom Medical is a Japanese company with 75 years of operation in Japan and 40 years in Europe. Their main activity is developing new technology for babies to help save infant lives. Mr. Bramato was familiar with the tender specifications.

The rotating mattress was not common in Europe, as there were no proven clinical benefits. Most standard worldwide guidelines require stable conditions in terms of humidity and temperature for the baby, very low noise, and only a minimal angle of inclination. The rotating mattress does not follow these guidelines because operating it requires opening an access door, which allows environmental air and noise to enter, and changes the baby's angle.

While referring to the guidelines, he mentioned the American Academy of Paediatrics, an internationally recognized authority providing basic information about the treatment of infants. The witness was asked to email these guidelines to the Board.

The product they manufacture can calculate humidity, ensures the baby does not hear extra noise during treatment, and reduces cross-infection risks due to its side design. Their product also reduces contamination risk because of the small sides of the mattress, and when the door is opened for access, the airflow automatically cuts off to minimize temperature loss inside the incubator. GE, a U.S. company, is the main supplier of incubators with rotating mattresses.

Regarding the weight issue, they believe that a 7kg range covers the normal weight of babies from delivery onward.

The product allows customers to set the temperature at least 5° higher than the ambient temperature, which is about 25°C. Inside the incubator, the temperature is maintained between 35°C and 38°C, which is within the operational range.

The tender specifies a temperature of 20°C, which is not ideal for a pre-term neonatal baby. The maximum setting of their product is 37°–38°C, while the minimum setting of the Incu model is 23°C.

Cross-Examination by Dr. Leon Camilleri.

Mr. Bramato confirmed that he represented Atom Medical Corporation and that he is an engineer, not a medical officer. Since GE are the main suppliers of rotating incubators in Europe, Dr. Camilleri asked whether the witness was excluding other manufacturers of rotating incubators.

The witness stated that he had not seen any similar products in Europe except those by GE. When asked whether the rotating mattress limits handling of the baby, he explained that while rotating, the baby is moved. The mattress rotates, not the entire system. The company he represents does not have a rotating system. He acknowledged that if a baby requires longer treatment, its weight will increase, though not significantly.

The witness stated that the temperature maintained in the incubator is 35°–38°C; however, the temperature range of their product is 23°–37°C. The 23°–25°C range is used for warming the system while waiting for the baby to arrive from the delivery room. Clinicians have never needed to use a temperature lower than 23°C.

Ms. Angie Haken (Passport No. 126036206) — Summoned by Dr. John Gauci.

Ms. Haken, a registered nurse since 1993, studied at Liverpool University. She has worked in paediatric and neonatal care and is currently a clinical senior specialist for Atom Medical, a position she has held since 2017. Her main responsibilities include providing clinical support and educational training in hospitals across the UK and Europe. She has extensive experience in Medical Trust Management and in the safe use of medical devices. She is also responsible for research and development projects for the company.

Ms. Haken stated that the rotating mattress feature, as reviewed from scientific and clinical literature, offers no proven clinical advantage in paediatric care. There are no studies indicating clinical improvements such as respiratory stability or enhanced liver regulation. None of these can be directly attributed to a rotating mattress feature.

She has written articles, though not specifically on incubators, and she reviews literature on market products and promotes those with clinical benefits. Dr. Gauci quoted:

‘This feature is very often utilised clinically by the doctors and the nurses, as it allows them to rotate the baby without having to handle the patient; this feature is required and is to remain as a mandatory requirement.’

The company that developed the rotating mattress was GE in the 1990s, introducing it as a design feature intended to enhance care. However, clinicians say that while it is a nice feature to have, it can be impractical in emergencies, as moving the patient takes time and can be cumbersome. Clinical staff report that it is not a smooth transition bed.

In the first seventy-two hours of life, babies should be kept in one position without disruption. Ms. Haken expressed concerns that the rotating bed could be jerky, and specialists told her that in an emergency, it is preferable to lift and move the baby manually. A jerky bed is not suitable when the baby’s brain is still immature.

The incubator is never used at a low temperature; the normal starting temperature is 35°–36.5°C, which is gradually lowered as needed but never below 23°C. Ms. Haken remarked that a large baby of 9kg would not fit in an incubator, and by about four months of age or 5kg weight, the baby is moved into a hospital cot, where additional therapies may be provided if required.

Cross-Examination by Dr. Leon Camilleri.

Ms. Haken stated that General Electric are still manufacturing rotating mattresses presently. In the UK, hospitals prefer to use high-quality incubators from Atom Medical. She believes a few manufacturers may have copied GE's design. She was not aware of any cases where the temperature in an incubator needed to be below 20°C.

When babies maintain their body temperature independently, clinicians lower the incubator temperature to above 30°C, confirming that the baby can self-regulate and stay out of the incubator. In the UK, when a baby reaches 1600g and can maintain temperature, they are moved to a cot.

For babies requiring hypothermia treatment, staff open the incubator canopy, insert cooling mattresses, and switch off the incubator. The temperature of 23°C is never used.

There are brands offering a range of 20°C to 39°C, but it is not clinically viable to work on a 9kg baby inside the confined space of an incubator. She confirmed that she works for Atom Medical Corporation, which produces neonatal incubators.

Dr. Camilleri noted that Dr. Ryan Farrugia was an important witness. Dr. Ryan Farrugia, a consultant and specification drafter, could not attend the hearing as he was conducting a seminar.

Verbal:

'The Contracting Authority is asking the Board to call Dr. Ryan Farrugia as their main witness for their proof. Dr. Camilleri and Dr. Farrugia Zrinzo informed the Board that the witness was unavailable for today's hearing. The appellant, Dr. Gauci, has no objection to postponing the hearing for continuation because of this point. The Board is upholding the request for deferral.'

Adjournment

It was agreed by all parties that the continuation of the appeal hearing would be held on Monday, 24th November 2025, at 7:30 a.m., to hear the testimony of Dr. Ryan Farrugia. The Chairman instructed Ms. Vella, a PCRB employee, to send invitations to all concerned parties.

Conclusion of the Hearing

The Chairman, Dr. Vincent Micallef, thanked all parties and formally concluded the session.

SECOND DAY – November 24, 2025.

On November 24, 2025, at 7:30 am, the PCRB reconvened to continue considering the appeal following the first hearing held on the 4th of November 2025.

The Board was composed of:

Dr Vincent Micallef – Chairman.

Ing. Dr Damien Gatt – Member.

Mr. Lawrence Ancilleri – Member.

The attendance for this public hearing was as follows:

Appellant – Reactilab Limited. (C56095).

Dr John L Gauci – Legal Representative. (online)
Mr Stefan Debono – Company Representative. (online)
Ms Nour Benmatoug – Company Representative. (online)

Contracting Authority – Central Procurement and Supplies Unit (CPSU).

Dr Alexia Farrugia Zrinzo – Legal Representative. (online)
Dr Leon Camilleri – Company Representative. (online)
Ing. Chris Attard Montalto -- Chief Biomedical Engineer and Spec Drafter. (online)
Ms Branica Amato Gauci – Head of Procurement. (online)
Ms Marika Cutajar – Procurement Manager. (online)
Dr Ryan Farrugia—Consultant & Spec Drafter. (online)

Department of Contracts.

Dr Mark Anthony Debono – Legal Representative. (online)
Dr Audrey Marlene Buttigieg Vella – Legal Representative. (online)

Recommended Bidder – Not Applicable.

Opening Statements.

Dr Vincent Micallef, Chairman of the Public Contracts Review Board, welcomed the parties present, namely the Appellant, Reactilab Limited, and the Contracting Authority, the Central Procurement and Supplies Unit (CPSU). The hearing was held online.

Initial Submissions.

The Chairman stated that an interim appeal had been filed by Dr Gauci for another witness to answer technical questions and invited Dr Gauci to make his initial submissions.

Dr Alexia Farrugia Zrinzo informed the Chairman that there were new developments on their side and called on Dr Leon Camilleri.

Dr Leon Camilleri informed the Board that the case involved three specifications, and the Contracting Authority had accepted variations in two of them.

The Chairman listed the three specifications, namely those concerning the weight, temperature, and the rotating mattress requirement.

Dr Camilleri clarified that the weight indicated by the Contracting Authority had been 300g – 9kg; however, the Contracting Authority changed it to 300g – 7kg

The Contracting Authority also accepted to amend the minimum temperature specification, changing 20°-- 39° to 23°-- 39°.

The specification concerning the rotating mattress was to remain unchanged.

Dr Gauci, for Reactilab Ltd., agreed with the amended specifications for the weighing scale and the temperature.

The Chairman noted that these two specifications were redundant and that the witness was to testify only on the rotatable mattress.

Dr Gauci stated that, in his testimony, Ing. Attard Montalto had named a number of compliant models, mainly the CAM1 of Ningbo. He had some photos to upload, and an email address was provided, and two photos were uploaded.

Dr Camilleri intervened and mentioned that Consultant Dr Ryan Farrugia was present to testify.

Witness.

Mr Stephen Debono (ID no. 47373M) — Summoned by Dr John Gauci.

Mr Stephen Debono, Managing Director of Reactilab Ltd., was responsible for the project. Referring to the Ningbo David YP3000,100B model, referred to as Doc CAM1, which can perform a 360° rotation, Mr Debono stated that he had attended the Medica Fair in Düsseldorf and had seen Ningbo's product. The representative at the stand permitted them to take a short video, which was being presented as an attachment to the Board.

Mr Debono stated that when the rotating mattress was in motion, the doll representing the baby remained facing the same direction, and the cable surrounding the rotating mattress was becoming stuck with the mattress. The representatives did not know how to use the rotating mattress in cases where the baby in the incubator required electrodes to be attached.

The Chairman asked for the video to be uploaded, and it was marked as JLG6.

Mr Debono noted that the video showed the pros and cons of the model, with the intention of providing the patient with the best possible care.

Ing. Dr Damien Gatt, member of the Board, clarified that in the last hearing they had been shown the Giraffe Model and the Satis 1, and they were now referring to the incubator CAM1.

Cross-Examination by Dr Leon Camilleri.

Dr Camilleri clarified with the witness that he was not a medical professional and that the product was sold by their competitors. The company importing the product into Malta was a scientific-sector company. The company Atom, owned by the witness, does not produce an incubator with a rotating mattress.

Witness.

Dr Ryan Farrugia (ID no. 183578M) — Summoned by Dr Leon Camilleri.

Dr Farrugia, a clinical lead at the NPICU and a consultant, is responsible for the Intensive Care of Neonatal and Paediatric Units. In Malta these two units are amalgamated for patients up to three years of age. Incubators are used for two reasons: to keep the baby warm and to serve as a barrier against infections, particularly for babies coming from home, especially in cases involving MRSA, a bacteria resistant to antibiotics.

A surface swab is taken, and the baby is kept in isolation until results are available. Since there are no single rooms for all babies, incubators are used in such cases. The rotating mattress provides the advantage of access to the baby from every angle without physically handling the baby, who often has tubes and catheters attached. Doctors may require assistance, and since the space is restricted, a rotating mattress is beneficial. This facility is currently in use and is very useful. Without it, the baby must be handled manually while attached to tubes, which is very dangerous. Premature babies become distressed when lifted, as they need full support on all sides, mimicking the womb environment.

This distress can cause increases in blood pressure and heartbeat and may lead to brain haemorrhage. Doctors may need to inject the baby in the foot or hand, attach tubes to the head, or insert a breathing tube. A rotating mattress allows the doctor access without requiring additional staff to handle the baby, saving precious time. Referring to the video, where the mattress rotated while the doll did not, Dr Farrugia stated that a real baby would rotate with the mattress, otherwise the purpose of the feature would be defeated.

Dr Farrugia further stated that handling a baby with leads attached is always challenging, and a rotating mattress is beneficial, as is already the practice in the ward.

Dr Farrugia Zrinzo for the Contracting Authority noted that the baby in the video was a mannequin and did not reflect real clinical conditions. Dr Ryan Farrugia added that the number of patients is increasing, and space is restricted. At times the medical team must work through portholes, making the ability to rotate the baby necessary to work from the sides.

Cross-Examination by Dr John L. Gauci.

Dr Gauci asked for clarification about incubators used for isolation from bacteria. Dr Farrugia explained that the NPICU is a unit for babies, and since there is no room to isolate babies coming from their environment, the doctors use incubators until bacterial tests are completed. The incubator contains any viruses present on the baby, preventing their spread.

At Mater Dei Hospital there are incubators with 360° rotating mattresses and others without. Incubators with a 360° rotating mattress are used for critically ill babies, for whom the function is essential.

Dr Farrugia had worked in a baby unit in England, where they had different models with different angles of rotation. In Malta, they use the Giraffe GE model with a rotating mattress. In severe cases, the incubator must be opened, even if equipped with a rotating mattress, as doctors need full access to treat the most urgent condition first.

Regarding the Ningbo model shown in the video, although the mannequin did not rotate with the mattress, the mattress itself does rotate as specified. The mannequin appeared to skid on the plastic surface; in reality, a baby would be placed on bed linen.

Dr Farrugia had experience with Atom models. These allow access from the sides and from the top; however, doctors rarely use the top access and instead need the option to raise the incubator to their level.

Ing. Attard Montalto had to leave the hearing for another meeting.

Ing. Dr Damien Gatt asked whether all ten incubators (CT2246/25) requested, needed to have rotating mattresses; Dr Farrugia insisted that they should all be identical.

Final Submissions by Dr John L. Gauci.

The economic operator requested that the three requisitions be amended so that the tender would not remain tailor-made. The hearing began with the applicant's amendments to two of the requisitions. From the

testimonies of both Dr Farrugia and Ing. Attard Montalto, it was clear that the tender was modelled on a model presently used at Mater Dei Hospital. The Contracting Authority stated that this was not the only model with these features.

Ing. Attard Montalto presented catalogues of various makes of incubators that would comply with the tender specifications, including the Ningbo model. Dr Gauci asked whether this product, manufactured in China, met all the technical specifications; Ing. Attard Montalto stated that he had contacted the dealer in Malta, who confirmed that the product was compliant.

Dr Gauci also questioned the engineer about the permissible weight limit of the GE Giraffe Incubator Care Station, where the maximum weight is eight kilos while the tender requested nine kilos. The only compliant model was the one belonging to his clients. His clients attended a trade fair, and although Dr Farrugia seemed to diminish the video, it must be remembered that demonstrating an incubator at a fair is difficult. It was shown during the hearing that the feature requested existed only in one manufacturer's product.

Referring to the Hill-Rom Cam 3 in a document exhibited by Ing. Attard Montalto, this indicated two different products sold by Peak Medical: the Hill-Rom, which was not compliant, and the Giraffe warmer, upon which the request was modelled. It is not permissible for a tender to be modelled on a particular product, and Reactilab was requesting that the specification be amended to allow greater competition, medically and clinically, enabling wider participation.

Final Submissions by Dr Leon Camilleri.

A key point was to address the models mentioned by Dr Gauci. The Contracting Authority does not evaluate models but specifications and objectives. The tender was published with a set of specifications, three of which were contested. The Contracting Authority was flexible and agreed to vary two specifications, but the rotating mattress specification was necessary.

He referred to Case Medina Ltd vs CPSU (June 2024) and quoted:

“Il-fatt li jista jkun hemm gustifikazzjoni ghax xkiel ghal access ugwali, jkompli juri li l'effetti anti kompetittivi ma huwiex ibso facto illecitu, huwa illecitu, meta, ma huwiex gustifikat b'ghanijiet legittimi”.

Every specification excludes any product that does not meet it. This specification has a legitimate aim, according to Ing. Attard Montalto and Consultant Dr Farrugia, because in severe cases, instead of handling the baby, the rotating mattress must be used.

They explained the distress caused to the baby when handled manually, the associated risks, and the limitations. The objection claimed that the rotating mattress was unmanageable when tubes and cables were present; however, Dr Farrugia stressed that handling a baby with cables manually was even more difficult. The mannequin not rotating in the video does not reflect real clinical circumstances.

Regarding competitiveness, both Ms Angie Haken and Ing. Attard Montalto stated that other companies producing rotatable mattresses exist. The allegation that the tender was modelled on a specific model was not proven. If this product were not successful, it would not have been manufactured since the 1990s.

The Contracting Authority ensures that tenders issued are competitive, and as the client, it must procure what it needs, as long as the specifications are justified. Since the requirement is legitimate, useful, and legal, the CPSU believes the request should be upheld.

Referring to the two amended specifications, Dr Camilleri suggested that the Board issue a clarification instead of cancelling the tender, in order to expedite the decision for the sake of patients.

Dr Audrey Marlene Buttigieg Vella from the Department of Contracts made no submissions.

Conclusion of the Hearing.

With no further arguments presented, Chairman Dr Vincent Micallef thanked the parties and formally closed the session

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 4th November, 2025 and of the 24th November, 2025, respectively.

Having noted the call for remedies filed by *Reactilab Limited* (hereinafter referred to as "*the Appellant*") on 16th September, 2025, refers to the claims made by the same Appellant with regard to the tender of reference *Call for Remedies 593 – CT2246/2025* listed as case No. 2177 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr John L. Gauci
Appearing for the Contracting Authority:	Dr Leon Camilleri and Dr Alexia J Farrugia Zrinzo
Appearing for the Department of Contracts:	Dr Mark Anthony Debono

Whereby, **the Appellant contends** that:

Whereas Applicant has identified certain technical specifications in the Tender that unduly restrict competition, specifically Spec No 2.3.2 requiring a rotatable mattress to allow access to the head for airway manoeuvres, Spec No 2.3.5 requiring an integrated weighing scale with a range of 300-9,000g ($\pm 100g$) and a resolution of 10g, and Spec No 2.4.1 requiring a convective heater allowing air temperature settings between 20 °C and 39 °C;

Whereas Applicant has observed from the tender clarification process that these specifications are overly restrictive and appear tailored to exclude technically and clinically equivalent alternatives, as evidenced by the Contracting Authority's refusal to consider any modifications or "or equivalent" solutions during clarifications;

Whereas such specifications are therefore unlawful, discriminatory and abusive in terms of both local and EU public procurement law;

Now therefore, Applicant submits the following:

Discriminatory Technical Specifications impeding Competition and therefore Unlawful

For the sake of clarity, this application for review is limited to the abovementioned technical specifications of Tender CT2246/2025, which the Applicant contends are drafted in a manner that unjustly limits competition. These are addressed in turn below.

1. The Rotatable Mattress Requirement (Spec No 2.3.2).

Applicant is particularly concerned with the Tender's stipulation mandating a *"rotatable mattress to allow access to the head for airway maneuvers."* This specific requirement is highly specific to a proprietary design of a single manufacturer and significantly restricts the field of potential suppliers.

In fact, one clarification query by a prospective bidder bluntly noted that this *"requirement is highly specific to certain proprietary designs and may significantly limit the number of suppliers able to participate... [I]f retained, competition would be extremely narrowed"*. Another inquiry explicitly pointed out that the rotatable mattress specification is a *"lockout"* feature *"pertaining to only one manufacturer (GE) and thus limits compliance... to only one potential bidder,"* rendering the practice *"unfair and biased"*. In other words, the feature appears to be uniquely offered by GE Healthcare in its neonatal incubators, meaning only GE's product (or a licensee thereof) can fully satisfy this criterion. Multiple prospective bidders during the clarification stage sought to have this requirement revised or clarified in order to open competition to functionally equivalent solutions.

For instance, one bidder respectfully requested that the specification *"be revised to focus on the functional outcome rather than prescribing a single mechanical solution to ensure fair competition"*. Similarly, another asked whether *"a fixed mattress design that still ensures full and unhindered access to the neonate's head area for airway management would be considered acceptable"*. These queries underscore that equivalent alternative designs exist - e.g. incubators with a fixed or slide-out mattress tray and well-placed access ports, which allow clinicians to perform airway manoeuvres without physically rotating the infant's bed. Such designs achieve the same clinical objective (unhindered access to the infant's airway) without the need for a rotating mechanism.

Despite these reasoned objections and proposals, the Contracting Authority responded with a rigid stance in each case. In Clarification Note 4, Clarification Note 5, and Clarification Note 6, the Authority gave an identical reply that *"this feature is very often utilised clinically by the doctors and the nurses, as it allows them to rotate the*

baby without having to handle the patient... this feature is required and is to remain as a mandatory requirement." Rather than addressing the substance of the concern - which is the disproportionate impact on competition - the Authority simply asserted clinical preference.

Applicant submits that this assertion is not supported by broad clinical practice. On the contrary, as the clarification questions themselves observed, using a rotatable mattress would require opening the incubator (to rotate the mattress apparatus), thereby disrupting the controlled environment and potentially destabilizing a fragile neonate. In practice, neonatal professionals can and do obtain access to an infant's head via portholes or by briefly opening an access panel when necessary, rather than rotating the entire mattress platform. The clinical necessity of a 360° rotatable mattress is therefore at best debatable, and certainly not so indispensable as to justify excluding all incubators that lack this feature. It is pertinent to note that the rotatable mattress feature in question is patented and proprietary to GE Healthcare's incubators.

This confirms that the design is unique to GE. By insisting on this exact feature, the Tender is effectively referring to a specific make or technology-namely, GE's incubator design - without allowing any equivalent solution. The outcome is that competition is unjustly restricted to the single supplier that incorporates this patented rotating mattress in its incubators.

This is precisely the kind of distortion that public procurement rules forbid, as will be detailed in the legal section below. Applicant further submits that contemporary neonatal care adheres to the principle of minimum handling, particularly in preterm infants fitted with catheters, SpO2 sensors and ventilator circuits. Neither AAP nor WHO guidance identifies a rotatable mattress as a recommended or necessary intervention for airway access. On the contrary, routine care-including airway manoeuvres and umbilical catheterisation can be safely performed through portholes or by briefly drawing out the mattress platform/tray where available, thereby avoiding disruption of the controlled environment and avoiding manipulation of lines. Applicant's proposed solution provides full patient access via a drawn-out platform, achieving the identical clinical outcome while respecting minimum handling.

1. The Weighing Scale Specification (Spec No 2.3.5)

The Tender also specifies that the incubator must include an integrated scale with a range of 300 g up to 9,000 g (± 100 g accuracy) and a resolution of at least 10 g. Applicant submits that this requirement is unnecessarily onerous and does not reflect actual clinical needs for neonatal intensive care, with the effect of excluding certain manufacturers for no justifiable reason.

In neonatal practice, it is exceptionally rare to care for infants anywhere near 9 kilograms in weight - such a weight would correspond to an older baby well outside the neonatal age range. Indeed, according to Malta's National Obstetric Information System (NOIS) statistics for 2023 (as referenced during the clarifications), the vast majority of newborns weigh on the order of 3 kg, with the most common birth-weight range being 3000-3499 g (over 43% of births). Only a tiny fraction of infants had extreme weights at birth - for example, only 11 babies (0.2%) were recorded at or above 4500 g- and virtually none would approach 9 kg.

A scale capacity of 7,000 g would therefore more than cover the neonatal population, including growth over the early weeks or months of life. Thus, the imposition of a 9,000 g scale capacity was questioned in Clarification Note 5, wherein the bidder suggested a scale up to 7,000 g with a finer resolution of 5 g as an alternative.

The rationale was that a higher resolution (smaller increment) is clinically desirable for premature infants, where tracking minute weight changes is critical. By contrast, the Tender's required 10 g resolution is coarser. The proposal thus offered a trade-off: a slightly lower maximum range (7 kg instead of 9 kg) in exchange for double the precision (5g instead of 10 g). From a clinical perspective, this is a sound compromise - 7 kg still encompasses all expected neonatal weights with ample margin, and improved precision would better support medical decisions regarding nutrition and fluid management for preterm babies.

However, the Contracting Authority summarily refused to consider this alternative, stating that "*the specifications are correct and are to remain as published.*" No justification was given for why an incubator must weigh up to 9 kg, nor why a 10 g resolution was deemed sufficient when finer scales are available.

Applicant is concerned that this specification, like the rotatable mattress, may have been lifted from a particular manufacturer's product data sheet without regard to actual needs effectively tailoring the tender to that product. If, for example, one leading brand's incubator happens to have a 9 kg/10 g scale, while others have (say) a 6 kg or 8 kg scale with finer readability, the tender is unnecessarily shutting out the latter offerings.

This lacks any objective justification linked to the contract's subject-matter (which is neonatal patient care). It is difficult to conceive of a scenario where a neonate in intensive care would require weighing up to 9 kilograms; on the other hand, the benefit of detecting a 5 g weight change in a 500 g micro-preemie is very concrete. By refusing to accommodate a better-resolution scale with a still-adequate range, the Contracting Authority is prioritizing an arbitrary numeric requirement over clinical functionality, to the detriment of competition.

2. The Temperature Range Specification (Spec No 2.4.1).

The Tender requires that the incubator be equipped with a convective heater permitting air temperature settings in the range of 20 °C to 39 °C. Applicant respectfully submits that this specification is not only clinically unnecessary but also potentially unsafe, and in any event unjustifiably restrictive of competition. During the clarification stage, prospective bidders expressly raised this concern, noting that the lower limit of 20 °C is inconsistent with accepted medical guidelines and actual clinical practice.

Reference was made to WHO and AAP/AHA guidelines, which recommend delivery room temperatures above 23-25 °C to reduce the risk of neonatal hypothermia. It was highlighted that, in practice, incubators are typically set in the 30-36 °C range, with 28 °C being the lowest used only in rare exceptional circumstances, and that no published study supports the safe use of incubator settings as low as 20 °C.

Furthermore, the only clinical scenario involving lowered body temperatures-therapeutic hypothermia-is carried out using specialised cooling devices such as cooling blankets, caps or whole-body systems, never by lowering the incubator's convective heating below safe thresholds. The clarification also explained that maintaining a minimum setting of 23 °C would be both clinically sufficient and more consistent with patient safety, while still fulfilling the stated purpose of the Tender, namely *"to provide an optimal thermal environment for sick and premature newborn infants"* Despite this evidence, the Contracting Authority refused to adjust the specification, simply replying that *"the specifications are correct and are to remain as published."* Applicant submits that the 20 °C requirement lacks any objective justification linked to the subject-matter of the contract.

On the contrary, it contradicts internationally recognised standards of neonatal care and exposes tenderers to a requirement that has no practical application in neonatal intensive care. By imposing a technically superfluous and medically questionable range, the Contracting Authority is in effect excluding from participation those manufacturers whose incubators are designed in line with best international practice (i.e. with a minimum setting of 23 °C), thereby unjustifiably narrowing competition. Accordingly, the requirement of a convective heater capable of operating at 20 °C constitutes a disproportionate and discriminatory specification, in breach of Regulation 53(6) and 53(8) of the Public Procurement Regulations.

Applicant therefore requests that the Board order the revision of Spec No 2.4.1 so as to permit incubators with a safe and clinically appropriate temperature range (for instance, 23 °C to 39 °C), in line with international guidelines and equivalent functional performance.

II. LEGAL BASIS AND JURISPRUDENCE

The above specifications, as currently formulated, violate fundamental procurement principles enshrined in law. Regulation 53(6) of the Public Procurement Regulations explicitly provides that "*Technical specifications shall afford equal access of economic operators to the procurement procedure and shall not have the effect of creating unjustified obstacles to the opening up of public procurement to competition.*"

Furthermore, Regulation 53(8) unambiguously prohibits contracting authorities from prescribing technical requirements that are tantamount to naming a brand or patent, except where absolutely necessary: "*Unless justified by the subject-matter of the contract, technical specifications shall not refer to a specific make or source, or a particular process... or to trade marks, patents, types or a specific origin or production with the effect of favouring or eliminating certain undertakings or certain products.*"

In the present case, the rotatable mattress requirement is essentially a reference to a patented feature of a specific make (GE) without any allowance for equivalents. There is nothing in the nature of a neonatal incubator that inherently requires a 360° rotating mattress - many incubators function optimally without that feature - thus it cannot be said that this specification is "*justified by the subject-matter of the contract.*"

Likewise, the 9,000 g scale requirement, in context, appears to have the effect of "*eliminating certain products*" (those with lower but sufficient weight ranges or higher precision) without objective necessity.

This Board has often emphasised the obligation to maintain open competition. In the decision delivered in *PCRB Case 1130 re: CT2233/2017*, this Board held that the Contracting Authority should "*do its utmost to allow equivalent products to participate and thus eliminate or suppress any limitation to free competition*".

In the present Tender, the Authority has done the opposite - it has refused to allow any equivalent solutions for the rotatable mattress (even where the same clinical aim would be met) and has refused to adjust the weighing scale specification (even when presented with an equivalent-or-better alternative). Such intransigence defeats the very purpose of competitive procurement, converting what should be an open tender into a de facto single-source requisition for the benefit of one brand.

This is in contravention of the principles of transparency, competition and equality of treatment as embodied in the Public Procurement Regulations and EU law.

III. REQUEST FOR REMEDIES

In view of the above grievances, and in terms of Regulation 262 of the Public Procurement Regulations, the Applicant humbly requests this Board to:

- (i) declare that the three impugned technical specifications - namely Spec No 2.3.2 requiring a rotatable mattress, Spec No 2.3.5 requiring an integrated weighing scale of 300-9000 g (± 100 g) with 10 g resolution, and Spec No 2.4.1 requiring a convective heater capable of settings down to 20 °C - are overly restrictive and unlawful, in that they violate the principles of open competition, equal access to the tender, and proportionality;
- (ii) order the removal or setting aside of these restrictive requirements from the Tender document;
- (iii) direct the Contracting Authority to revise the specifications in question so as to permit functionally equivalent solutions - by inter alia, allowing an incubator design that provides full airway access to the patient without a rotatable mattress; allowing an integrated weighing scale with an adequate neonatal range (up to ~7 kg) and allowing a convective heater specification with a clinically appropriate and safe range (for instance 23 °C to 39 °C) rather than an arbitrary 20 °C minimum, in line with international guidelines and actual neonatal practice;
- (iv) order a corresponding extension of the deadline for submission of tenders;
- (v) take any other measures deemed necessary to ensure that the tendering process is brought back in line with the applicable law and remains inclusive of a wider array of potential suppliers and technologies.
- (vi) order the refund of the deposit paid in conjunction with the Application; Applicant reserves the right to make further observations and to submit evidence furtherance of the above.

This Board also noted the Contracting Authority's **Reasoned Letter of Reply** filed on the 22nd September, 2025 and its verbal submissions during the hearing of the 4th November, 2025 and the 24th November, 2025 respectively, in that:

On the 7th of August, 2025, a call for tenders for the Supply of Closed Type Neonatal Incubators for the Neonatal and Paediatric Intensive Care Unit at Mater Dei Hospital was published with a number of specifications.

The applicant felt aggrieved by a number of specifications, which it insists that are not required, and filed the present appeal. DOC and CPSU humbly disagree with the application and are filing the below submissions in reply, in the same order of the issues raised by the applicant:

Submissions:

Preliminary

The applicant filed its application in terms of regulation 262 of the PPR. Regulation 262 provides an exhaustive list of situations in which this remedy could be sought, however the applicant failed to indicate the paragraph on which they are basing their application. For this reason alone, the application should be declared as inadmissible as the requests can never be upheld in the absence of an indication of the legal basis.

On the Specifications subject to this Application

The Applicant is contesting the below 3 specifications: 3.3.2 - Rotatable mattress to allow access to the head for airway manoeuvres 2.3.5 - The incubator should feature an integrated weighing scale with range 300- 9,000g \pm 100g with a resolution of a minimum of 10g 2.4.1 - Convective heater allowing air temperature settings between 20 °C to 39 °C 4 The applicant states that these technical specifications are unlawful, discriminatory and abusive and states that these impede competition and are therefore unlawful.

DOC and CPSU submit that all specification, from their very nature put a restriction on participants which do not fulfil such specifications, however this does not necessarily mean that such specifications are unlawful, discriminatory or abusive as long as there is a clinical and practical justification for the specification imposed.

The Court of Appeal in its decision of the 24th of June, 2024 in the names *Medina Limited vs Central Procurement and Supplies Unit*, stated that:

9. *"Fi kliem iebor, il-fatt wahdu li l-kondizzjonijiet tas-sejba jistghu jnaqqsu l-kompetizzjoni mbux biżżejjed biex il-kondizzjoniet tas-sejba jitqiesu bi ksur tar-reg. 39(3). Kondizzjoni fsejha li trid li oblatur ikollu ċerta esperjenza jew li jkollu ċerta sabha finanzjarja jnaqqsu l-kompetizzjoni ghax jeskludu oblaturi minghajr l-esperjenza jew is-sabha finanzjarja mehtieġa; ma jfissirx iżda illi huma ipso facto bi ksur tar-regolament, sakemm ma jintweriex illi dik il-kondizzjoni ddabblat b'dak ilbsieb.*

10. *Dan jobrog aktar car fir-reg. 53(6): >53. (6) L-ispeċifikazzjonijiet tekniċi ghandhom joffru aċċess ugwali tal-operaturi ekonomiċi għall-proċedura ta' akkwist u ma ghandux ikollhom l-effett li jolqgħu xkiel minghajr ġustifikazzjoni għall-ftuh tal-akkwist pubbliku għall-kompetizzjoni.*

11. *Il-fatt li jista' jkun hemm "ġustifikazzjoni" ghax-xkiel għal aċċess ugwali jkompli juri illi l-effett anti-kompetitiv ma huwiex ipso facto illeċitu; huwa illeċitu meta ma huwiex "ġustifikat" b'għanijiet legittimi.*

12. *Għalhekk, għalkemm huwa minnu illi l-prova tal-intenzjoni soġġettivament diżonesta mhix mehtieġa, ghax jista' jirriżulta oġġettivament illi l-kondizzjonijiet tas-sejba ma seta' kellhom ebda għan*

iehor, madankollu leffett anti-kompetitiv, ghalkemm jista' jobloq prova prima facie ta' intenzjoni projbita, madankollu huwa biss wiehed mill-fatturi li ghandhom jitqiesu, u prova tal-intenzjoni anti-kompetitiva tixxejjien jekk jintwera illi l-kondizzjoni dabblet b'ghan legittimu”.

DOC and CPSU will be below explaining the reasons for such technical specifications; Rotatable mattress to allow access to the head for airway manoeuvres

A rotatable mattress has various benefits, particularly that it Facilitates Airway Manoeuvres. The ability to rotate the mattress allows healthcare providers to easily access the infant's head and neck to perform necessary airway interventions.

Moreover, the rotating mattress Reduces the Risk of Injury. Positioning the baby in different angles or rotations minimizes the need to manually adjust the baby, thus reducing the risk of accidental injury during critical procedures.

Additionally, rotating the mattress can help achieve an optimal head position, improving airflow and enabling better ventilation as will be explained in more details by the clinicians during the sitting.

All of these benefits prove that this clause is legitimate and justifiable, made in the best interests of the patients which in the present case are neonatal babies.

Moreover, and without prejudice to the above, DOC and CPSU submit that it is not true that the product is intended to the limit the competition to one manufacturer.

For the above reasons, as will be further expounded on during the sitting this grievance should be rejected. The incubator should feature an integrated weighing scale with range 300 9,000g \pm 100g with a resolution of a minimum of 10g.

Although DOC and CPSU do not contest the fact that a neonatal in the range of 9kg is very rare, the fact remains that this is a possibility that can happen and thus the contracting authority is seeking to procure a product which caters for such eventuality.

Moreover, as will be explained during the sitting there might be rare scenarios that a baby remains in critical condition, and this would need to remain in an incubator when it is weighing more than the normal weight of neonatal infants.

Since the technology exists, and contrary to what is being claimed by the objector, not by one supplier, the contracting authority decided to purchase the incubators with scales of such capacity to cater for these rare but possible scenarios.

Moreover, what the applicant is requesting is an *ad hoc* specification for its product. If the Contracting authority requested an integrated scale with a range of up to 8,000 grams, the applicant's product would most probably still not be in line with the specification. If the contracting authority requested an integrated scale with a range of up to 7,000 grams, suppliers of smaller ranges could still potentially object claiming discrimination in their product's regard;

The contracting authority's main argument is therefore that a line should be drawn somewhere and drawing a line is not discriminatory or abusive but is part of the natural obligation of the contracting authority in placing certain limitations to define what it is seeking to purchase.

For the above reasons as will be further expounded on during the sitting this grievance should be rejected. Convective heater allowing air temperature settings between 20 °C to 39 °C. The applicant argues that this particular specification is unsafe as 20°C is a very low temperature for a neonatal.

The fact that the equipment has a range of 20 °C to 39 °C does not mean that it will be used on 20 °C, however a range would always allow for the clinical possibility in case there is a need to use temperatures lower than usual.

For the above reasons, as will be further expounded on during the sitting this grievance should be rejected. For the above reasons and submissions which will be further explained and evidenced during the sitting, DOC and CPSU humbly requests that the application ought to be rejected and the tender document confirmed as published. DOC and CPSU reserves the right to present evidence and to make additional submissions, orally or in writing and to present evidence to sustain its position.

The Board notes that the Appellant filed a further application requesting the Board's leave to grant the Appellant permission to summon an additional witness contending:

Whereas during the last sitting of these proceedings, the representative of the Contracting Authority, Ing. Chris Attard Montalto, presented documentary evidence consisting of technical product documentation relating to third-party brands;

Whereas such documentation had not been made available to the parties in anticipation of the sitting, contrary to the usual practice and directions of this Honourable Board, which consistently orders advance circulation of documentary evidence;

Whereas the documentation presented was described, by the Contracting Authority, as intended to demonstrate that the Tender specifications were not tailor-made, and included various comparative technical sheets, including documentation relating to a particular model namely the YP-3100B Ningbo David;

Whereas the late production of this material deprived the Applicant of the opportunity to verify and address it adequately during the sitting, although the Applicant has since carried out the necessary technical examination of this particular model;

Whereas in order to ensure fairness of process, and given that the Board has not yet commenced the hearing of evidence on behalf of the Contracting Authority, it is both appropriate and procedurally efficient that the Applicant be permitted to offer a brief testimony to clarify and address, solely and specifically, the YP-3100B Ningbo David documentation now produced;

Therefore, Applicant humbly requests that this Honourable Board to:

- i. Authorize the Applicant's representative to testify briefly (approximately 10 to 15 minutes) for the sole purpose of addressing the technical characteristics of the model YP-3100B Ningbo David found in the documentation produced for the first time at the last sitting;
- ii. Allow such testimony to be taken prior to the commencement of the evidence of the Contracting Authority;
- iii. Direct that this matter be dealt with during the next scheduled sitting, which is a virtual hearing set for Monday, 24th November, 2025 at 7:30 a.m.
- iv. Give any further directions it deems fit.

The Board delivered an interim decree in line with *Regulation 90(4)* of the *Public Procurement Regulations* in that it decided:

DECREE

Having seen the application filed by Reactilab Limited in the records of FW: Case 2177 – (593) – CT2246/2025 – Tender for the Supply of Closed Type Neonatal Incubators for the Neonatal and Paediatric Intensive Care Unit at Mater Dei Hospital

Having taken cognisance of the submissions made therein;

Having further taken note of the declaration made by the representative of the Contracting Authority during the last sitting of these proceedings, wherein several sets of technical product documentation, relating to various third-party brands, including the model YP-3100B Ningbo David, were presented for the first time during the sitting itself;

The Board observes that such documentation was not circulated to the parties in advance, contrary to the long-standing directions and established practice of this Board, which consistently orders the prior transmission of documentary evidence so that all parties may prepare accordingly. The Board comments that this late presentation ought not to have occurred;

The Board further notes that, in view of this late production of technical material, the Applicant was fully entitled to request the opportunity to submit brief evidence;

The Board also acknowledges that the Contracting Authority did not object to the request made by the Applicant, but instead expressly deferred to the Board's determination on the matter;

Therefore, and particularly given the technical nature of the documentation produced, the Board considers it appropriate to accede to the Applicant's request;

For these reasons, the Board hereby upholds the Applicant's request as contained in the application dated 19th November, 2025.

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 as follows in their entirety.

I. Introduction

This decision arises from an application for review submitted by the Appellant pursuant to *Regulation 262* of the *Public Procurement Regulations*, concerning *Tender CT2246/2025* for the supply of closed-type neonatal incubators for the Neonatal and Paediatric Intensive Care Unit at Mater Dei Hospital. The Appellant contends that certain technical specifications contained in the Tender are unduly restrictive, discriminatory, and designed in a manner that significantly narrows the field of potential suppliers, thereby infringing upon the principles of transparency, equal treatment, and open competition enshrined in both domestic and European public procurement law.

The application specifically challenges three provisions of the Tender, namely, the requirement for a rotatable mattress to facilitate airway manoeuvres (*Spec No 2.3.2*), the stipulation regarding an integrated weighing scale with a range of 300–9,000 grams and a minimum resolution of 10 grams (*Spec No 2.3.5*), and the convective heater specification with a temperature range of 20 °C to 39 °C (*Spec No 2.4.1*). The Appellant asserts that these provisions are disproportionate, technologically prescriptive, and, in certain

instances, refer to proprietary features or thresholds that do not reflect actual clinical needs, thereby potentially excluding functionally equivalent alternatives and restricting genuine competition.

The Department of Contracts (DOC) and the Central Procurement and Supplies Unit (CPSU), maintains that the contested specifications are justified by legitimate clinical and functional objectives, that they do not prescribe a particular manufacturer or proprietary technology, and that they serve to safeguard patient welfare in accordance with internationally recognised neonatal care standards. The Authority further asserts that the specifications are formulated in a manner that balances clinical necessity with the operational scope of the tender and that any perceived restriction of competition is both inadvertent and proportionate.

Against this backdrop, the Board has undertaken a meticulous examination of the written submissions, documentary evidence, and oral arguments presented during the hearing of 4th of November, 2025 and the 24th November, 2025. In performing this task, the Board is mindful of its duty to assess not only the formal compliance of the specifications with the *Public Procurement Regulations* but also their substantive effect on market access, functional adequacy, and proportionality in achieving the objectives of the procurement.

In this context, the Board's consideration of each contested specification necessarily entails a dual lens, *first*, the assessment of whether the specification is objectively justified by the subject matter of the contract and the legitimate clinical aims of neonatal care, and *second*, whether it imposes any disproportionate or discriminatory constraint on potential suppliers.

This introduction, therefore, sets the stage for a detailed analysis of each specification challenged by the Appellant, followed by a robust discussion of the relevant legal framework, jurisprudential guidance, and the Board's reasoned consideration, culminating in the Board's final determination and orders.

II. Discriminatory Technical Specifications Impeding Competition

Preliminary Objection – *Admissibility*

The DOC raised a preliminary objection contending that the Appellant's application fails the procedural requirements of *Regulation 262*, specifically for not indicating the exact sub-paragraph of the Regulation under which relief is sought. The Board observes that while *Regulation 262* sets out precise procedural grounds for remedies, the Appellant has provided a detailed grievance submission demonstrating a *prima facie* concern regarding unlawful or disproportionate specifications that may restrict competition. The substance of the application is sufficiently clear to engage the Board's jurisdiction and, accordingly, the preliminary objection is rejected.

1. The Rotatable Mattress Requirement (Spec No 2.3.2)

The Appellant contends that the Tender's specification requiring a *"rotatable mattress to allow access to the head for airway manoeuvres"* is unduly restrictive, being highly specific to a proprietary design of a single manufacturer, GE Healthcare. The Appellant submits that this requirement effectively narrows the field of potential suppliers and constitutes a *de facto* preferential treatment, thereby undermining the principles of fair and open competition. During the clarification process, multiple prospective bidders highlighted that the stipulation *"may significantly limit the number of suppliers able to participate,"* describing it as a *"lockout feature"* that favours the products of a single manufacturer.

In response, the Appellant proposed that alternative designs, including fixed or slide-out mattress trays, could achieve the same clinical objectives, namely, unhindered access to the infant's airway, without necessitating rotation of the mattress, thereby providing functionally equivalent solutions while broadening market participation.

The Appellant further emphasised that the Contracting Authority's repeated assertions, as reflected in Clarification Notes 4, 5, and 6, that the rotatable mattress is *"very often utilised clinically by doctors and nurses"* and constitutes a preferred feature, fail to address the central concern raised, that the specification disproportionately restricts competition.

The Appellant underlined that contemporary clinical guidelines and best practice standards, including those promulgated by the *World Health Organization* and the *American Academy of Paediatrics*, do not prescribe the use of a rotatable mattress as an essential intervention for airway access. On the contrary, neonatal care principles such as minimum handling can be achieved safely using alternative designs, which allow full access to the neonate's head without rotation, thereby maintaining clinical safety and efficacy while ensuring that the specification does not operate as a barrier to entry for other suppliers.

The Department of Contracts and the Contracting Authority, in rebuttal, asserts that the rotatable mattress facilitates airway manoeuvres, reduces the risk of injury during positioning, and optimises head placement for improved ventilation. It maintains that these objectives are legitimate clinical goals, and that the specification is intended to serve patient safety rather than to favour any particular supplier.

Technical Evidence:

Ing. Chris Attard Montalto provided testimony, based on market research, demonstrating that multiple suppliers, including *Infant Incubator YP-3100B*, *Satis+ Ref3600*, and *Hill-Rom Incubator*, offer comparable functionality with rotatable mattresses. The Board notes that while this evidence confirms the availability of the feature across multiple brands, it does not purport to establish full compliance across all tender specifications, which include mandatory parameters such as double-walled transparent compartments, air temperature control, integrated weighing scales, and ergonomic requirements.

Board's Considerations:

The Board has carefully considered the competing testimonies heard during the sitting held on the 4th November, 2025 and additional witnesses and material presented during the sitting of 24th November, 2025, particularly insofar as they relate to Specification 2.3.2 concerning the rotatable mattress.

To begin with, the Board notes that the model referenced by Ing. Attard Montalto, namely the YP-3100B Infant Incubator (marked as CAM 1 in the acts), was the subject of substantial challenge by the Appellant.

Mr Stephen Debono, testifying for the Appellant, recounted his direct visit to the manufacturer's stand at the medical trade fair in Düsseldorf, where he physically inspected the cited model and requested clarification on its features. He further exhibited a video recording taken at said stand. Although the product literature indicates that the model is equipped with a rotatable mattress, the video portrayed a scenario in which the mattress rotates mechanically, but the neonate placed upon it does not rotate. In practical terms, the device appears to lack the capability of rotating the neonate itself, an aspect central to the Contracting Authority's own interpretation of the specification.

Dr Ryan Farrugia, Consultant and Clinical Lead and appearing as witness for the Contracting Authority, rebutted the implications of the video and maintained that, in proper use, the neonate would indeed rotate.

The Board need not resolve this factual divergence in order to decide the present grievance. What matters for the present purposes is not whether a particular demonstration video captured a perfect or imperfect use of a device, but whether, when read cumulatively, the tender specifications, as drafted, operate to restrict, or effectively close off, competition.

The Board fully acknowledges that the Contracting Authority enjoys broad discretion to design technical specifications in accordance with its clinical needs. That discretion, however, is not unfettered. It must be exercised in a manner consistent with the principles of proportionality, equal treatment, and the widest possible competition. A specification may be demanding, indeed, it may be very demanding, provided that its stringency is justified and does not, in substance, reduce the tender to a direct order dressed in procurement language.

Having examined the full suite of specifications, clarifications, and technical dossiers, the Board is not satisfied that Specification 2.3.2, in its existing formulation, preserves that balance. The evidence before the Board shows that, notwithstanding the theoretical availability of rotatable mattress systems, the precise configuration demanded, when read together with the other mandatory features, even by setting aside the dispute concerning the YP-3100B, the cumulative effect of the specification, particularly as clarified by the Contracting Authority during the process, narrows the competitive field to such an extent that participation becomes effectively exclusive.

Moreover, the Board notes that, save but the testimony of Dr Ryan Farrugia, throughout the appeal's proceedings, the Contracting Authority did not furnish any reference to "*international standards*", recognised "*clinical guidelines*", or "*peer-reviewed literature*" demonstrating that a rotatable mattress is required, or even recommended, as part of established neonatal care practice.

By contrast, the appellant substantiated his arguments with reference, *inter alia*, to Malta's National Obstetric Information System (NOIS) statistics for 2023, as well as to guidelines issued by the World Health Organization and the American Academy of Pediatrics/American Heart Association.

No documents issued by authoritative bodies such as the *World Health Organization*, the *American Academy of Paediatrics*, the *European Foundation for the Care of Newborn Infants*, or equivalent professional associations were cited to substantiate that rotation of the mattress constitutes a clinically essential feature. This absence of objective, evidence-based justification further underscores that the inclusion of a rotatable mattress is not grounded in an identifiable clinical necessity. In procurement terms, the lack of such justification reinforces the Board's finding that Specification 2.3.2, as drafted, operates as an unwarranted and disproportionate restriction on competition.

Such an outcome is incompatible with the foundational principle that public procurement must remain open, genuinely competitive, and non-proprietary unless strict and well-justified reasons dictate otherwise. The Board must also be mindful that clinical functionality, here, the requirement that mattresses be rotatable and serve their clinical purpose, can often be safeguarded without prescribing a design so specific that only one or very few economic operators can possibly comply.

In this respect, the Board observes that the Contracting Authority could have preserved its legitimate clinical objectives while still broadening market participation through alternative drafting approaches, including, but not limited to, the following:

- *Functional or performance-based criteria* (e.g., requiring the system to enable safe and effective repositioning of the neonate), rather than prescriptive mechanical configurations.
- *Structuring the tender in lots*, separating the incubator units from specialized mattress systems, thereby enabling a wider set of suppliers to compete for distinct components without the need for full proprietary integration.
- *Allowing clinically equivalent solutions* that achieve the same neonatal rotation outcome, even if through different mechanical means, provided they meet established safety and ergonomic parameters.

Such approaches would have safeguarded the Contracting Authority's clinical needs, including those articulated by Dr Farrugia, without imposing an unnecessarily narrow technical path that only one or few manufacturers can traverse.

In light of all this, the Board finds that the Appellant has convincingly demonstrated that Specification 2.3.2, as currently framed, exerts a disproportionate restrictive effect on competition. The tender, if upheld in this form, risks functioning as a *de facto* sole-source procurement, contrary to the spirit and letter of the *Public Procurement Regulations*.

Accordingly, the Board determines that Specification 2.3.2 cannot be maintained in its present formulation.

2. The Weighing Scale Specification (Spec No 2.3.5)

The Appellant contends that the specification requiring an integrated weighing scale with a range of 300–9,000 grams (± 100 grams) and a minimum resolution of 10 grams is both clinically unnecessary and disproportionately restrictive of competition.

Drawing upon empirical data from the *Maltese National Obstetric Information System (NOIS)*, the Appellant highlights that the overwhelming majority of neonates are born within the 3,000–3,499gram range, representing over 43% of births in 2023, and that cases of neonates approaching or exceeding 9 kilograms are vanishingly rare. In light of this, the Appellant argues that requiring an incubator scale capable of registering up to 9 kilograms unnecessarily excludes equipment designed for more typical clinical circumstances, while failing to provide any material benefit in terms of patient care. Moreover, the Appellant submits that a more precise scale, with a resolution of 5 grams, would be clinically advantageous for extremely low-birth-weight neonates, allowing practitioners to monitor minute weight variations that are critical for decisions relating to nutrition, fluid management, and growth monitoring, yet would simultaneously broaden participation in the tender.

During the clarification process, prospective bidders proposed adjustments, including a reduction of the maximum weighing range to 7,000 grams while improving resolution, demonstrating the existence of functionally equivalent alternatives. The Appellant submits that the Contracting Authority's refusal to entertain these alternatives, with the assertion that the original specifications "*are correct and are to remain as published,*" exemplifies an inflexible approach that prioritises numeric thresholds over actual clinical utility, and which, if left unamended, risks constituting an artificial constraint on market participation.

The Contracting Authority, in response, emphasised that while neonates exceeding typical weights are rare, the specification accounts for exceptional clinical circumstances in which a heavier infant remains in critical care and must continue to be accommodated within the incubator. The Authority asserts that the required technology is available from multiple suppliers, and that the specification is neither brand-specific nor intended to confer advantage upon a single manufacturer. Furthermore, it contends that drawing the line

at a particular maximum weight is an inherent and legitimate part of defining procurement requirements, necessary to delineate the object of the contract and ensure clarity in bidding.

Board's Considerations

The Board observes that while the upper limit of 9,000g may theoretically account for rare clinical contingencies, this requirement appears disproportionate when evaluated against the standard clinical reality of neonatal care. Empirical evidence, including data from *Malta's National Obstetric Information System* (NOIS) for 2023, demonstrates that the vast majority of neonates admitted to intensive care units weigh between 3,000g and 3,499g, with only an exceedingly small fraction exceeding 4,500g, and virtually none approaching 9,000g. Accordingly, a scale capacity of approximately 7,000g would, with ample margin, accommodate virtually all neonates, including those experiencing postnatal growth or requiring extended intensive care.

Beyond mere weight range, the Board notes that the resolution requirement of 10g merits scrutiny. Precision in weighing neonates is clinically significant, particularly for preterm infants whose nutritional management, fluid balance, and growth monitoring depend on minute weight variations. The Appellant has convincingly argued, and the Board concurs, that a finer resolution (e.g., 5g) is available in contemporary devices and would provide superior clinical utility without compromising safety or operational feasibility. In contrast, the current specification prioritises a coarser numeric threshold, which may inadvertently favour certain suppliers whose equipment aligns with these arbitrary parameters, rather than prioritising devices with enhanced clinical functionality.

From a public procurement perspective, the Board emphasizes the principle of proportionality and non-discrimination. Technical specifications must be objectively justified by the subject-matter of the contract and not designed in a manner that excludes otherwise compliant suppliers. In this case, the requirement to accommodate an exceptionally high and statistically improbable weight, combined with a resolution that does not reflect best clinical practice, imposes an undue restriction on competition without commensurate operational or clinical benefit. Such an approach risks violating *Regulation 53(6) of the PPR*, which mandates that technical specifications afford equal access and avoid creating unjustified barriers to participation.

That said, however, and further to the above, the Board notes that during the sitting held on 24th November, 2025, and before a final decision is delivered on the merits of this appeal, the Contracting Authority declared and confirmed, on a preliminary basis, its intention to amend the tender specifications by reducing the upper weight limit from 9,000 g to 7,000 g, while retaining the minimum weight threshold of 300 g.

This proposed adjustment effectively addresses the Appellant's grievance concerning the disproportionate upper limit, as discussed in the preceding paragraphs. Consequently, with this forthcoming modification,

the concern raised regarding Specification 2.3.5 becomes largely redundant, as the revised range aligns with realistic neonatal weight distributions and preserves both clinical relevance and operational feasibility.

3. The Convective Heater Specification (Spec No 2.4.1)

The Appellant challenges the requirement that the neonatal incubator's convective heater permit air temperature settings between 20 °C and 39 °C. It is submitted that the minimum threshold of 20 °C is clinically superfluous and potentially unsafe, as standard neonatal care guidelines, including those of the *World Health Organization* and the *American Academy of Paediatrics*, recommend higher minimum ambient temperatures, typically not below 23–28 °C, for delivery rooms and neonatal incubators.

The Appellant notes that in practice, incubators are commonly set within the 30–36 °C range, with temperatures below 28 °C utilised only in highly exceptional and carefully controlled circumstances.

The Appellant argues that the 20 °C requirement could exclude incubators designed in accordance with internationally recognised neonatal standards, thus imposing an unnecessary limitation on market participation without corresponding clinical benefit. The Appellant further contends that this requirement, if enforced rigidly, introduces the risk of misapplication or confusion, particularly for suppliers whose designs comply fully with best practice but do not offer such an extreme low-end setting.

In response, the Contracting Authority asserts that the 20 °C minimum is included to provide maximum flexibility for rare clinical scenarios, without implying that operation at such a low temperature would be routine. It is submitted that the requirement is not intended to favour any particular manufacturer, but rather to safeguard patient outcomes by ensuring that incubators can accommodate exceptional circumstances.

Board's Considerations

The Board observes that *Specification 2.4.1* mandates a convective heater capable of delivering air temperature settings between 20 °C and 39 °C. While the upper limit is uncontroversial, the Board finds that the lower limit of 20 °C lacks any demonstrable clinical justification within the context of neonatal intensive care.

Established international standards, including guidance from the *World Health Organization (WHO)* and the *American Academy of Paediatrics (AAP/AHA)*, recommend environmental temperatures above 23–25 °C for the prevention of neonatal hypothermia. Empirical practice further indicates that incubators are typically maintained within the 30–36 °C range, with temperatures below 28 °C being virtually unused except in rare, highly controlled scenarios. Thus, the 20 °C floor constitutes a clinically superfluous and potentially unsafe setting, which is not reflective of standard neonatal care practice.

The Board further considers that the inclusion of this extreme lower threshold may operate as a technical barrier to competition. Incubator models designed in accordance with prevailing clinical guidelines may not provide such low temperature settings, and yet are otherwise fully compliant with the functional and safety requirements of neonatal intensive care. By insisting on a minimum of 20 °C, the Contracting Authority may inadvertently exclude technologically and clinically equivalent devices from consideration, thereby narrowing competition without a proportionate clinical rationale.

In this regard, the Board recalls that the objective of technical specifications is to ensure functional adequacy without unduly favouring or disadvantaging particular suppliers, consistent with *Regulations 53(6) and 53(8) of the Public Procurement Regulations*.

That said, however, and further to the above, the Board notes that during the sitting held on 24th November, 2025, the Contracting Authority preliminarily and before a final decision is delivered on the merits of this appeal declared and confirmed its intention to amend Specification 2.4.1 by raising the minimum air temperature setting from 20 °C to 23 °C, while retaining the maximum of 39 °C. This proposed adjustment effectively addresses the Appellant's grievance concerning the clinically inappropriate lower threshold. Consequently, with this forthcoming modification, the concern raised regarding Specification 2.4.1 becomes redundant, as the revised temperature range aligns with established neonatal care standards and preserves both functional adequacy and fair competition.

III. Legal Framework

The Board recalls that, under the Public Procurement Regulations, technical specifications are a critical instrument in defining the subject matter of a contract. They serve to ensure that procured goods or services meet the requisite functional and quality standards necessary to achieve the contracting authority's legitimate objectives.

However, in performing this function, specifications must also respect the fundamental principles of public procurement, foremost among which are transparency, equal treatment, and open competition. *Regulation 53(6) of the Public Procurement Regulations* expressly provides that technical specifications shall “*afford equal access of economic operators to the procurement procedure*” and must not “*have the effect of creating unjustified obstacles to the opening up of public procurement to competition.*” In essence, any requirement which, by its formulation or effect, unduly narrows the pool of potential suppliers without objective justification, risks contravening this principle.

In conjunction with this, *Regulation 53(8)* imposes a further limitation on contracting authorities by prohibiting the inclusion of specifications that effectively prescribe a particular make, source, patented feature, or proprietary process, save where such a requirement is demonstrably justified by the subject matter of the contract. The rationale underpinning this provision is that procurement must operate in a

manner that fosters competition and innovation, while preventing public contracts from being indirectly channelled to a specific manufacturer or technology, absent compelling technical necessity.

Jurisprudence, both domestic and at the European level, has further refined the application of these provisions. It establishes that the mere existence of a restriction on competition is not, in itself, unlawful but, rather, such restrictions are only impermissible when they lack objective justification. The Courts and Review Bodies have consistently emphasised that contracting authorities retain discretion to define specifications that are necessary to meet legitimate functional, safety, or operational requirements. Nonetheless, that discretion is constrained by the overarching obligations of proportionality and non-discrimination, specifications that achieve a legitimate aim but do so in a manner that is excessive or unnecessarily exclusive may still constitute an unlawful impediment to competition.

Accordingly, in assessing the technical specifications challenged in this appeal, the Board has applied this framework with rigorous attention to both the functional objectives of the tender and the need to preserve broad and fair access to the market. The Board has examined whether the contested requirements are objectively justified by the subject matter of the contract, whether they are proportionate to the needs of neonatal care, and whether they unduly restrict the participation of otherwise capable suppliers.

IV. Conclusions

Upon comprehensive examination of the pleadings, technical evidence, and clarifications furnished by the parties, the Board is satisfied that each of the contested specifications warrants separate and distinct consideration, guided by the principles of proportionality, non-discrimination, and legitimate clinical necessity underpinning public procurement law.

1. Rotatable Mattress Requirement (Spec No 2.3.2)

The Board finds that the tender's specification mandating a rotatable mattress to allow head access for airway manoeuvres is disproportionately restrictive. While intended to serve legitimate clinical objectives, the specification is overly prescriptive, effectively narrowing the field of potential suppliers and risking *de facto* preferential treatment. The Board concludes that Specification 2.3.2, in its current formulation, unduly limits competition and cannot be maintained. Functional or performance-based criteria, or a separation of components into lots, could meet clinical needs while broadening supplier participation.

2. Weighing Scale Specification (Spec No 2.3.5)

The requirement for an integrated scale with a 300–9,000 g range (± 100 g) and 10 g resolution is deemed clinically disproportionate. Empirical data indicate that the majority of neonates fall between 3,000–3,499 g, with neonates approaching 9 kg being exceptionally rare. A scale with a 7,000 g maximum and finer

resolution (e.g., 5 g) would accommodate virtually all cases while enhancing clinical utility and broadening competition. However, the Board notes that during the 24th November, 2025, sitting, the Contracting Authority preliminarily indicated its intention to reduce the maximum weight to 7,000 g while retaining the 300 g minimum. This amendment addresses the Appellant's grievance, rendering the concern regarding Specification 2.3.5 largely redundant.

3. Convective Heater Specification (Spec No 2.4.1)

The minimum temperature threshold of 20 °C in the incubator's convective heater specification is clinically unnecessary and potentially unsafe. Standard neonatal care guidelines recommend minimum ambient temperatures above 23–25 °C, and in practice incubators are usually set between 30–36 °C. The 20 °C requirement could exclude devices compliant with best practice, creating an undue barrier to competition. However, the Board notes that on 24th November, 2025, the Contracting Authority preliminarily indicated its intention to raise the minimum temperature to 23 °C, retaining the 39 °C maximum. This adjustment effectively resolves the Appellant's grievance, making the concern regarding Specification 2.4.1 redundant while maintaining clinical adequacy and fair competition.

The Board,

Having evaluated all the above and based on the above considerations, concludes and decides:

- a) To uphold the Appellant's concerns and grievance on *Spec No 2.3.2*, relating to the rotatable mattress, as it does constitute an unlawful restriction and in its current formulation, it unduly limits competition and cannot be maintained. Functional or performance-based criteria, or a separation of components into lots, could meet clinical needs while broadening supplier participation.
- b) To abstain from taking further cognizance of the Appellant's concerns and grievance on *Spec 2.3.5*, relating to the integrated weighing scale since the Contracting Authority preliminarily declared and confirmed its intention to reduce the maximum weight to 7,000 g while retaining the 300 g minimum. This amendment addresses the Appellant's grievance, rendering the concern regarding *Specification 2.3.5* largely redundant. However, the Board emphasizes that, should the Contracting Authority fail to implement this amendment as declared, the existing specification, in its current form, constitutes a disproportionate restriction on competition and shall not remain. The Board accordingly orders that the revised range be reflected in the tender to ensure functional adequacy, clinical relevance, and open competition.
- c) To abstain from taking further cognizance of the Appellant's concerns and grievance on *Spec 2.4.1*, relating to the convective heater specification since the Contracting Authority preliminarily

declared and confirmed its intention to the Contracting Authority preliminarily indicated its intention to raise the minimum temperature to 23 °C, retaining the 39 °C maximum. This adjustment effectively resolves the Appellant's grievance, making the concern regarding *Specification 2.4.1* redundant while maintaining clinical adequacy and fair competition. Nevertheless, the Board underlines that, in the event the Contracting Authority does not implement this declared change, the existing minimum threshold of 20 °C constitutes an unjustified restriction on competition. The Board therefore directs that the revised minimum of 23 °C be applied to safeguard both clinical standards and equitable market participation.

- d) To amend the '*Closing Date of the Call for Tenders*' to the 5th January, 2026.
- e) after taking all due consideration of the circumstances and outcome of this Call for Remedies, directs that the deposit be refunded to the Appellant in its entirety.

Dr Vincent Micallef
Chairman

Mr Lawrence Ancilleri
Member

Ing Dr Damien Gatt
Member